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TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No. 36956.1000

In Re Application Of: **Kenneth V. Buer et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/066,024	January 29, 2002	Pablo N. Tran	20322	2685	2094

Invention: **HIGH POWER BLOCK UPCONVERTER**

COMMISSIONER FOR PATENTS:

Transmitted herewith ~~in triplicate~~ is the Appeal Brief in this application, with respect to the Notice of Appeal filed on

March 9, 2005

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Dated: **May 9, 2005**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

Appellants:	**Kenneth V. Buer et al.**	**Docket No.:**	**36956.1000**
Serial No.:	**10/066,024**	**Group Art Unit:**	**2685**
Filed:	**January 29, 2002**	**Examiner:**	**Pablo N. Tran**

TITLE: **HIGH POWER BLOCK UPCONVERTER**

TO: Mail Stop Appeal Brief - Patents
Commissioner for Patents
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APPELLANTS' BRIEF PURSUANT TO 37 C.F.R. § 1.192

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PATENT

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APPELLANT'S BRIEF PURSUANT TO 37 C.F.R. § 1.192

Honorable Commissioner:

Appellants appeal the decision of the Examiner finally rejecting all pending claims in the present application, namely claims 1-6. Appellants timely filed their Notice of Appeal on March 9, 2005 in the United States Patent and Trademark Office.

I. REAL PARTY IN INTEREST

U.S. Monolithics L.L.C. is the real party in interest in the subject application, by virtue of an Assignment from inventors Kenneth V. Buer, Richard S. Torkington, and Edwin Jack Stanfield to U.S. Monolithics L.L.C. dated January 25, 2001. U.S. Monolithics L.L.C. is a wholly owned subsidiary of ViaSat, Inc.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences which will affect or be affected by the outcome of this appeal.

III. STATUS OF CLAIMS

Claims 1-6 are pending and rejected in this application. Appellant hereby appeals the rejection of all pending claims.

IV. STATUS OF AMENDMENTS

No amendments have been made to originally filed Claims 1-6. Claim 7 was cancelled in an amendment mailed May 9, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The pending application relates to a high power, surface-mountable converter for mixing a sub-harmonic local oscillator signal with an intermediate frequency (IF) signal to produce a radio frequency signal at millimeter wave bands.[1] The system 100 combines a high power block up-converter 104, an IF multiplexer 102, an RF multiplexer 106, a low noise block down-converter 108, an antenna 110, and a cable.[2] The high power block up-converter system 200 includes a mixer 202, driver amplifiers 204 and 206, a filter 208, a power amplifier 210, and a local oscillator (LO) amplifier 212.[3]

Mixer 202 provides the up-convert function of a signal from an IF frequency using a LO signal from LO amplifier 212.[4] Mixer 202 includes a sub-harmonic up-convert mixer to reduce the LO frequency needed at the external interface.[5] Furthermore, in various embodiments, the sub-harmonic mixer is a "high frequency mixer, such as a gallium arsenide MMIC-based subharmonic mixer."[6]

Filter 208 is configured to reject "unwanted spurious signals resulting from mixer 202."[7] In various embodiments, filter 208 is a band pass filter.[8] In various other embodiments, the filter is a hairpin suspended stripline band pass filter.[9]

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[1] See Specification page 3, lines 14-18.
[2] See Specification, page 4, lines 5-8; see also Figure 1.
[3] See Specification, page 5, lines 9-11; see also Figure 2.
[4] Id., lines 15-16.
[5] Id., lines 16-18; see also claim 2.
[6] Specification, page 6, lines 20-21; see also Figure 3, reference numeral 302.
[7] Specification, page 6, lines 4-5.
[8] See Id.
[9] See Specification, page 7, lines 8-9; see also Figure 3, reference numeral 308.

Power amplifier 210 is configured for high power multi-stage amplification, and "transmits the RF signal directly to the antenna without further RF amplification."[10] In various embodiments, the high power amplifier is configured to provide a 15 dB signal gain, and comprises "a 4 watt gallium arsenide MMIC based amplifier."[11] In one embodiment, power amplifier 310 is connected to an insert 311.[12] Insert 311 comprises a material having high thermal conductivity (e.g., a metallic material) to divert heat away from power amplifier 310, and also exhibits thermal expansion properties that substantially match the material of power amplifier 310 (e.g., gallium arsenide).[13]

Furthermore, the high power block up-converter system includes a chassis and a cover.[14] The chassis and cover are secured together to substantially encase the high power block up-converter system.[15]

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by E.P.O. Patent No. EP0624004A1 issued to Devlin, et al. ("Devlin").

Claims 2-6 stand rejected under 35 U.S.C. § 103(a) as being obvious over Devlin in view of the ordinary skill in the art.

VII. ARGUMENT

A. Overview Of The Invention

The present invention is directed to a high power block-up converter and a method for up-converting radio frequency (RF) signals to high frequency millimeter-wave or higher band RF signals. Features of the high power block-up converter of the present invention that are distinguishable over the prior art, and particularly, Devlin include:

1) A mixer configured to receive an intermediate frequency signal and a local oscillator signal, and output a millimeter-wave or higher band RF signal;

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[10] Specification, page 6, lines 6-9.
[11] Specification, page 7, lines 13-15; see also Figure 3, reference numeral 310.
[12] See Specification, page 7, line 19; see also Figure 3.
[13] See Specification, page 7, line 20 – page 8, line 2.
[14] See Figures 4b, 5a, and 5b.
[15] See Id.; see also claim 5.

2) A high power amplification device to receive the millimeter-wave or higher band RF signal, and provide a desired signal gain such that no further signal amplification is required prior to transmission in the millimeter-wave or higher band;

3) A sub-harmonic mixer;

4) An insert coupled to the high power amplification device; and

5) An insert coupled to the high power amplification device, wherein the insert comprises a material characteristic of high thermal conductivity and thermal expansion properties.

Features of the method for signal up-conversion of the high power block-up converter that are distinguishable over Devlin include:

1) Mixing a sub-harmonic local oscillator signal with an intermediate frequency signal to generate an RF signal within a millimeter-wave band;

2) Amplifying the millimeter-wave band RF signal such that no further signal amplification is required prior to transmission in the millimeter-wave band; and

3) Substantially encasing a high power block-up converter.

Millimeter-wave frequencies, as recited in claims 1-6, are known in the art as frequencies in the range of about 30-300 gigahertz (GHz)[16]. Devlin discloses a device operating only at 2.4 GHz,[17] a full order of magnitude less than that defined in claims 1-6. Furthermore, "high power" is known in the art as a relative term that depends on frequency. As discussed in greater detail below, the claimed block-up converter operates at 30 GHz or higher, and is considered a "high power" block-up converter. A device operating at 2.4 GHz, such as the device taught in Devlin, is considered a "low power" device.

B. Overview Of Devlin

Devlin teaches "an integrated transceiver circuit packaged component including a transceiver circuit having a filter provided therein for filtering both the received and transmitted

[16] See Millimeter Wave Propagation: Spectrum Management Implications, Abstract; see also page 1, lines 1-3.

signals to remove unwanted components therefrom."[18] "Preferably, the filter is a bandstop filter."[19] Devlin discloses two filters for his device, an external band pass filter (reference numeral 1) located off-chip, and a band-stop filter (reference numeral 29) located on-chip.[20] On-chip filter 29 "rejects the image/unwanted sideband (at frequency LO –IF) but does nothing to reject harmonic/spurious responses at other frequencies."[21] The off-chip, external filter 1 "serves this purpose."[22]

The device in Devlin is designed to address series feedback between each and every pin of the transceiver package caused by common lead inductance in low cost packaging.[23] Devlin notes that "just 0.2nH will act as -20 dB of feedback (considering a 50 ohm source and load impedances) at 2.4 GHz (the USA's ISM frequency band)."[24]

As such, the Devlin device focuses on reducing the feedback in low power, low cost packages operating in the ISM frequency band (i.e., 2.4 GHz.), and does not teach a device operating in millimeter-wave or higher frequency bands (i.e., 30 GHz to 300 GHz). Thus, Devlin teaches a device operating at frequencies at least one order of magnitude lower than frequencies in the 30 GHz to 300 GHz millimeter-wave band.

C. Claims Rejected Under 35 U.S.C. § 102(b)

To sustain an anticipation rejection, the Examiner must establish that "the invention was patented or described in a printed publication in this or a foreign country...more than one year prior to the date of the application for patent in the United States".[25] "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[26] To anticipate a claim for a patent, a single prior source must contain each of its limitations.[27] In other words, "*every* limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim."[28] "To anticipate a

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[17] See Devlin, Col. 2, lines 8-10.
[18] Devlin, Col. 2, lines 32-37.
[19] Id., Col. 2, line 38.
[20] See Col. 1, lines 3-16 and Col. 3, lines 4-8.
[21] Devlin Col. 3, lines 14-17.
[22] Id., Col. 3, lines 17-18.
[23] See Devlin, Col. 2, lines 3-8.
[24] Col. 2, lines 8-10.
[25] 35 U.S.C. § 102(b).
[26] Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).
[27] Hybridtech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1376, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); In re Donohue, 766 F.2d 531, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985).
[28] Gechter v. Davidson, 116 F.3d 1454 (Fed. Cir. 1997) (emphasis added).

claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter."[29]

1. Claim 1

Claim 1 stands rejected under 35 U.S.C. § 102 (b) as being anticipated by Devlin. Appellants respectfully traverse the rejection.

Among other elements, claim 1 defines "a surface-mountable high power block upconverter (HP-BUC) comprising a mixer configured to receive an IF frequency signal and a local oscillator signal and to output an RF frequency signal; said RF frequency signal comprising a frequency in a millimeter-wave or higher band" (emphasis added). Appellants submit that Devlin fails to teach at least a mixer configured to output a frequency in a millimeter-wave or higher band, as defined in claim 1.

As briefly discussed above, the millimeter-wave band is known in the art as including frequencies in the range of about 30 GHz to about 300 GHz.[30] In fact, the Federal Communications Commission's Office of Engineering and Technology, in Bulletin 70 entitled "Millimeter Wave Propagation: Spectrum Management Implications", declared:

> The millimeter wave spectrum at 30-300 GHz is of increasing interest to service providers and systems designers because of the wide bandwidths available for carrying communications at this frequency range. Such wide bandwidths are valuable in supporting applications such as high speed data transmission and video distribution.
>
> Planning for millimeter wave spectrum use must take into account the propagation characteristics of radio signals at this frequency range. While signals at lower frequency bands can propagate for miles and penetrate more easily through buildings, millimeter wave signals can travel only a few miles or less and do not penetrate solid materials very well. ...Millimeter waves can permit more densely packed communications links, thus providing very efficient spectrum utilization, and they can increase security of communication transmissions.[31]

In making the rejection, the Examiner mischaracterized Devlin as "having a mixer configured to receive an IF frequency signal and a local oscillator signal and outputs an RF

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[29] PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558 (Fed. Cir. 1996).
[30] Millimeter Wave Propagation: Spectrum Management Implications, page 1, lines 1-16.
[31] Page 1, lines 1-16.

frequency signal within a millimeter wave or higher band (fig. 3, col. 1/ln. 41-col. 2/ln. 11, col. 3/ln. 22-49)."[32] However, the sections cited by the Examiner, and Devlin as a whole, teach only a device configured to output a 2.4 GHz signal.[33] There is simply no teaching in Devlin of any output frequency, let alone frequencies greater than 2.4 GHz, and certainly no teaching of frequencies in the millimeter-wave and higher bands. In view of the qualitative differences between the "millimeter-wave spectrum" (30 GHz to 300 GHz) and lower frequencies discussed the Federal Communications Commission's Office of Engineering and Technology Bulletin, a 2.4 GHz signal device performs fundamentally different functions than a device operating in the millimeter-wave or higher band. For example, millimeter-wave and higher frequency signals provide improved propagation characteristics, greater spectrum utilization efficiency, and increased security features when compared to lower frequency signals. As such, a mixer configured to output a 2.4 GHz signal can not anticipate or render obvious a mixer configured to output a signal in a millimeter-wave or higher band.

In addition, claim 1 recites the elements of "a filter configured to receive said RF frequency signal and filter unwanted spurious signals which may be present in said RF frequency signal." Appellants submit Devlin fails to teach such a filter.

In making the rejection, the Examiner does not indicate how or where Devlin teaches these elements. Appellants submit that since Devlin fails to teach a device that outputs RF signals in the millimeter-wave or higher bands, Devlin cannot teach a filter configured to receive an RF signal in the millimeter-wave or higher band and filter unwanted spurious signals. Furthermore, the device in Devlin asserted to reject harmonics/spurious responses is an off-chip, external filter,[34] and cannot be considered part of a high power block-up converter since an off-chip, external device cannot be part of the device itself.

Furthermore, the elements of claim 1 define a high power block-up converter, whereas Devlin teaches a device that outputs a 2.4 GHz signal, which Appellants submit is a low power device. Devlin is completely silent regarding power. However, one of ordinary skill in the art would appreciate that the device disclosed in Devlin is a low power device. Therefore, Devlin fails to teach a high power block-up converter, as defined in claim 1.

In view of the foregoing, Appellants respectfully submit that Devlin fails to disclose each

[32] Paper No. 20050104, page 2.
[33] See Devlin, Col. 2, lines 8-10.
[34] See Devlin, Col. 1, lines 3-5 and 31-33; Col. 3, lines 4-8 and 17-18; Figures 1 and 3, reference numeral 1 in each.

of the elements of claim 1 and, therefore, Devlin can not anticipate claim 1 or claims 2-6, which variously depend therefrom.

D. Claims Rejected Under 35 U.S.C. § 103(a)

To sustain an obviousness rejection, the Examiner has the initial burden to establish a *prima facie* case of obviousness.[35] To establish a *prima facie* case of obviousness, 1) the prior art reference must teach or suggest all of the claim limitations, and 2) there must be some suggestion or motivation, either in references themselves or in the knowledge generally available in the art, to modify the reference.[36] Furthermore, the mere fact that references can be modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the modification.[37] Moreover, "because the references relied upon teach that all of the aspects of the invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references."[38] Appellants respectfully submit:

1) Devlin in view of the ordinary skill in the fails to teach or suggest each of the elements of claims 2-6 for reasons similar to claim 1 discussed above, in addition to their own respective features; and

2) There is no suggestion or motivation to modify the low power, low frequency device disclosed in Devlin to read on the high power, high frequency devices defined in claims 2-6.

1. Claim 2

The Examiner rejects claim 2 under 35 U.S.C. § 103 (a) as being anticipated by Devlin. Appellants respectfully traverse the rejection.

Claim 2 depends from independent claim 1 and includes all of the elements thereof. Therefore, Appellants respectfully submit that the discussion above regarding Devlin failing to teach or suggest 1) a mixer configured to output a signal with a frequency in a millimeter-wave or higher band, 2) a filter configured to receive said RF frequency signal and filter unwanted

[35] M.P.E.P. § 2142.
[36] See MPEP § 2143
[37] See MPEP § 2143.01.
[38] Id.

spurious signals, and 3) a high power block-up converter is equally applicable to dependent claim 2.

The Examiner provides no specific reference to the ordinary skill in the art for its purported teaching of a mixer configured to output a frequency in a millimeter-wave or higher band, a filter configured to receive the millimeter-wave or higher band signal and filter unwanted spurious signals, or a high power block-up converter. Furthermore, Appellants respectfully submit that it is not within the ordinary skill in the art to configure a mixer to output a frequency in a millimeter-wave or higher band, configure a filter to receive signal and filter unwanted spurious signals to form a high power block-up converter. Therefore, the combination of Devlin in view of the ordinary skill in the art fails to teach or suggest at least these elements of claim 2.

In addition, claim 2 recites "said mixer comprises a subharmonic mixer." The Examiner acknowledges that Devlin does not specifically disclose that the mixer in Devlin "is of a sub-harmonic type."[39] Furthermore, Appellants have reviewed Devlin in its entirety and agree with the Examiner that Devlin fails to teach or suggest a sub-harmonic mixer. The Examiner relies on the ordinary skill in the art to cure the defects of Devlin, however, Appellants respectfully submit the ordinary skill in the art fails to cure such defects.

In making the rejection, the Examiner takes official notice that sub-harmonic mixers are well known in the art, and that it would have been obvious to replace the mixer of Devlin with a sub-harmonic mixer to ensure that the harmonic is not generated in the mixer, and provide that the sub-harmonic mixer operates with an identical frequency harmonic of the local oscillator.[40] Appellants submit that the Examiner is using impermissible hindsight reconstruction in view of Appellants' disclosure in making such an assertion regarding the ordinary skill in the art and the motivation to modify Devlin.

Appellants submit that configuring a sub-harmonic mixer to receive an intermediate frequency signal and a local oscillator signal, and output a millimeter-wave or higher band radio frequency signal is not well known in the art. Appellants submit the Examiner is using the fact that a sub-harmonic mixer may be known in the art to read on a sub-harmonic mixer being used to receive an intermediate frequency signal and a local oscillator signal, and output a millimeter-wave or higher band RF signal. Even though one skilled in the art may know the components, and may be even be capable of modifying the components, these facts alone are not enough to

[39] Paper No. 20050104, page 3.

render these elements obvious because "the mere fact that references can be...modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination [or modification],"[41] and simply "because the references relied upon teach that all of the aspects of the invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references."[42]

Appellants submit that Devlin does not present such a motivation. Indeed, Devlin is concerned with low frequencies and the low frequency mixer disclosed in Devlin is appropriate for such applications. In contrast, claim 2 recites frequencies in the millimeter-wave and higher frequency bands, where it is desirable to use a "high frequency mixer, such as a gallium arsenide MMIC-based subharmonic mixer."[43] Therefore, there would be no motivation for one skilled in the art to replace the low frequency mixer in Devlin with a high frequency subharmonic mixer. As such, Devlin in view of the ordinary skill in the art fails to teach or suggest at least these elements of claim 2.

The failure of Devlin in view of the ordinary skill in the art to teach or suggest all of the elements of claim 2 is fatal to the obviousness rejection. Thus, Appellants respectfully submit claim 2 was improperly rejected.

2. Claim 3

The Examiner rejects claim 3 under 35 U.S.C. § 103 (a) as being anticipated by Devlin. Appellants respectfully traverse the rejection.

Claim 3 depends from independent claim 1 and includes all of the elements thereof. Therefore, Appellants respectfully submit that the discussion above regarding Devlin failing to teach or suggest 1) a mixer configured to output a signal with a frequency in a millimeter-wave or higher band, 2) a filter configured to receive said RF frequency signal and filter unwanted spurious signals, and 3) a high power block-up converter is equally applicable to dependent claim 3. Therefore, Devlin fails to teach or suggest at least these elements of claim 3.

The Examiner does not cite to the ordinary skill in the art for teaching a mixer configured to output a frequency in a millimeter-wave or higher band, a filter configured to receive the

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[40] See Id.
[41] MPEP § 2143.
[42] MPEP § 2143.01.

millimeter-wave or higher band signal and filter unwanted spurious signals, and a high power block-up converter. Furthermore, Appellants respectfully submit that it is not within the ordinary skill in the art to configure a mixer to output a frequency in a millimeter-wave or higher band, configure a filter to receive signal and filter unwanted spurious signals to form a high power block-up converter. Therefore, the combination of Devlin in view of the ordinary skill in the art fails to teach or suggest at least these elements of claim 3.

In addition, claim 3 recites the elements of "an insert coupled to said high power amplification device." Appellants' specification states, "insert 311 provides an attachment surface for power amplifier 310."[43] Appellants submit Devlin in view of the ordinary skill in the art fails to teach or suggest these elements.

In making the rejection, the Examiner acknowledges that Devlin fails to teach or suggest an insert. Appellants agree with the Examiner that Devlin fails to teach or suggest these elements. The Examiner relies on the ordinary skill in the art to cure the defects of Devlin, however, Appellants submit the ordinary skill in the art fails to do so.

The Examiner takes official notice asserting that it would have been obvious to add an insert to limit power dissipation and improve heat dissipation within the device.[44] Appellants note that the disclosure in Devlin suggests that the power amplifier (reference numeral 17) is directly attached to the package. Appellants submit there is no motivation to modify Devlin to include an insert to attach power amplifier 17 to the package because the package operates at such low frequencies. By contrast, claim 3 recites an insert to attach a high power amplification device to the high power block-up converter because the high power amplification device is configured to amplify high frequencies. Therefore, there is no motivation for attaching a power amplifier used to amplify low frequency signals to the package with an insert for attaching a high power amplification device for amplifying high frequency signals.

The failure of Devlin in view of the ordinary skill in the art to teach or suggest all of the elements of claim 3 is fatal to the obviousness rejection. Thus, Appellants respectfully submit claim 3 was improperly rejected.

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[43] Specification, page 6, lines 20-21.
[44] See Paper No. 20050104, page 3.

3. Claim 4

The Examiner rejects claim 4 under 35 U.S.C. § 103 (a) as being anticipated by Devlin. Appellants respectfully traverse the rejection.

Claim 4 depends from claim 3, which depends from claim 1, and includes all of the elements of claims 1 and 3. Therefore, Appellants respectfully submit the discussion above regarding the combination of Devlin and the ordinary skill in the art failing to teach or suggest all of the elements of claims 1 and 3 is equally applicable to dependent claim 4. Therefore, claim 4 is not obvious over the cited references.

In addition, claim 4 recites the elements of, "said insert comprises a material characteristic of high thermal conductivity and thermal expansion properties." The Examiner takes official notice asserting that it would have been obvious to add an insert to limit power dissipation and improve heat dissipation within the device.[45] Appellants submit that there is no motivation to modify the teachings of Devlin to include a thermal conductive and thermal expansive insert.

Appellants' specification states that "insert 311 may exhibit thermal expansion properties that substantially match the material of power amplifier 310, e.g., gallium arsenide," and "...provides heat conduction by 'spreading' generated heat away from power amplifier 310."[46] Appellants respectfully submit that there is no motivation for one skilled in the art to add such an insert to Devlin because the amount of heat generated by the power amplifier in Devlin does not warrant such a modification. Appellants' insert is included to spread the heat generated by an amplification device configured to amplify high frequency signals. Therefore, the combination of Devlin and the ordinary skill in the art fails to teach or suggest at least these elements of claim 4 because there is no motivation to modify the device in Devlin to include a heat dissipating insert to attach power amplifier 17 to the package.

The failure of Devlin in view of the ordinary skill in the art to teach or suggest all of the elements of claim 4 is fatal to the obviousness rejection. Thus, Appellants respectfully submit claim 4 was improperly rejected.

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[45] See Id.

[46] Specification, page 7, line 21 – page 8, line 2.

4. Claim 5

The Examiner rejects claim 5 under 35 U.S.C. § 103 (a) as being anticipated by Devlin. Appellants respectfully traverse the rejection.

Claim 5 depends from independent claim 1 and includes all of the elements thereof. Therefore, Appellants respectfully submit that the discussion above regarding Devlin failing to teach or suggest 1) a mixer configured to output a signal with a frequency in a millimeter-wave or higher band, 2) a filter configured to receive said RF frequency signal and filter unwanted spurious signals, and 3) a high power block-up converter is equally applicable to dependent claim 5. Therefore, Devlin fails to teach or suggest at least these elements of claim 5.

The Examiner does not cite to the ordinary skill in the art for teaching a mixer configured to output a frequency in a millimeter-wave or higher band, a filter configured to receive the millimeter-wave or higher band signal and filter unwanted spurious signals, and a high power block-up converter. Furthermore, Appellants respectfully submit that it is not within the ordinary skill in the art to configure a mixer to output a frequency in a millimeter-wave or higher band, configure a filter to receive signal and filter unwanted spurious signals to form a high power block-up converter. Therefore, the combination of Devlin in view of the ordinary skill in the art fails to teach or suggest at least these elements of claim 5.

In addition, claim 5 recites the elements of "a chassis and a cover." Appellants have reviewed Devlin in its entirety and submit there is no teaching or suggestion of 1) a chassis, and 2) a cover since Devlin discloses an open package. Therefore, Appellants respectfully submit Devlin fails to teach or suggest all of the elements of claim 5.

The failure of Devlin in view of the ordinary skill in the art to teach or suggest all of the elements of claim 5 is fatal to the obviousness rejection. Thus, Appellants respectfully submit claim 5 was improperly rejected.

In addition, Appellants respectfully submit the Examiner has failed to establish a *prima facie* case of obviousness in accordance with MPEP § 2143 because the Examiner has not stated that each of the elements of claim 5 are taught or suggested by the prior art. Therefore, Appellants respectfully submit the Examiner has made an improper obviousness rejection of claim 5. Therefore, claim 5 is not obvious over the cited references and was improperly rejected.

5. Claim 6

Claim 6 stands rejected under 35 U.S.C. § 103 (a) as being anticipated by Devlin. Appellants respectfully traverse the rejection.

Among other elements, independent claim 6 defines "a method for signal upconversion in a high power block upconverter (HP-BUC) comprising mixing a subharmonic local oscillator signal with an intermediate frequency signal to generate a radio frequency (RF) within a millimeter-wave band." Appellants have addressed the teachings of Devlin and the ordinary skill in the art above and submit that the discussion above regarding these references failing to teach or suggest at least a device that generates an RF signal within a millimeter-wave band is equally applicable to similar elements recited in claim 6. Therefore, Devlin in view of the ordinary skill in the art fails to teach or suggest at least these elements of claim 6.

In addition, claim 6 recites "amplifying said RF signal such that no further signal amplification is required prior to transmission in the millimeter-wave band." Appellants have reviewed Devlin and submit there is no teaching or suggestion of amplifying an RF signal within a millimeter-wave band such that no further signal amplification is required prior to transmission because Devlin only teaches operating in low frequencies (2.4 GHz) and does not, explicitly or implicitly, teach or suggest that a signal being transmitted from T/R common port 5 does not require further amplification, Devlin is simply silent on the matter. Moreover, Appellants submit the ordinary skill in the art does not include amplifying a high frequency signal without the need of further amplification. Therefore, at least these elements of claim 6 are not taught or suggested by Devlin and/or the ordinary skill in the art.

Furthermore, claim 6 recites, "substantially encasing said HP-BUC." Appellants submit that Devlin teaches a low power device for reasons similar to those discussed above. In contrast, claim 6 defines encasing a high power block-up converter. Therefore, Appellants submit at least these elements of claim 6 are not taught or suggested by Devlin and/or the ordinary skill in the art.

The failure of Devlin in view of the ordinary skill in the art to teach or suggest all of the elements of claim 6 is fatal to the obviousness rejection. Thus, Appellants respectfully submit claim 6 was improperly rejected.

VIII. CONCLUSION AND RELIEF

For the above reasons, Appellant requests that the Board overturn the rejection of all pending claims and hold that all of the claims are in condition for allowance.

Dated: May 9, 2005

Respectfully submitted,

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IX. CLAIMS APPENDIX

1. (Original) A surface-mountable high power block upconverter (HP-BUC) comprising:

a mixer configured to receive an IF frequency signal and a local oscillator signal and to output an RF frequency signal, said RF frequency signal comprising a frequency in a millimeter-wave or higher band;

a filter configured to receive said RF frequency signal and filter unwanted spurious signals which may be present in said RF frequency signal; and

a high power amplification device receiving said RF frequency signal and providing a desired signal gain such that no further signal amplification is required to said RF frequency signal prior to transmission in said millimeter-wave or higher band.

2. (Original) The HP-BUC of claim 1, wherein said mixer comprises a subharmonic mixer.

3. (Original) The HP-BUC of claim 1, further comprising an insert coupled to said high power amplification device.

4. (Original) The HP-BUC of claim 3, wherein said insert comprises a material characteristic of high thermal conductivity and thermal expansion properties.

5. (Original) The HP-BUC of claim 1, further comprising a chassis and a cover, whereby said chassis and said cover are secured together to substantially encase said HP-BUC.

6. (Original) A method for signal upconversion in a high power block upconverter (HP-BUC), said method comprising:

mixing a subharmonic local oscillator signal with an intermediate frequency signal to generate a radio frequency (RF) signal within a millimeter-wave band;

filtering said RF signal of any unwanted spurious signals;

amplifying said RF signal such that no further signal amplification is required to said RF frequency signal prior to transmission in said millimeter-wave band; and

substantially encasing said HP-BUC to make a stand-alone HP-BUC component, whereby said stand-alone HP-BUC component can be surface-mounted to other components.

7. (Cancelled)

X. EVIDENCE APPENDIX

1. Millimeter Wave Propagation: Spectrum Management Implications; Federal Communications Commission – Office Of Engineering and Technology; Bulletin Number 70; July 1997.

2. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

3. *Hybridtech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1376, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986).

4. *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985).

5. *Gechter v. Davidson*, 116 F.3d 1454 (Fed. Cir. 1997).

6. *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558 (Fed. Cir. 1996).

FEDERAL COMMUNICATIONS COMMISSION

OFFICE OF ENGINEERING AND TECHNOLOGY

Bulletin Number 70

July, 1997

Millimeter Wave Propagation: Spectrum Management Implications

Federal Communications Commission
Office of Engineering and Technology
New Technology Development Division
Mail Stop Code 1300-E
Washington, DC 20554

ABSTRACT

The spectrum between 30 GHz and 300 GHz is referred to as the millimeter wave band because the wavelengths for these frequencies are about one to ten millimeters. Millimeter wave propagation has its own peculiarities. This paper reviews the characteristics of millimeter wave propagation, including free space propagation and the effects of various physical factors on propagation. It was created to provide an easy to understand reference explaining the characteristics of radio signal propagation at millimeter wave frequencies and their implications for spectrum management.

The information presented should be useful to frequency managers, system designers, policy makers, and users of millimeter wave communications.

Prepared by New Technology Development Division, OET

INTRODUCTION

The millimeter wave spectrum at 30-300 GHz is of increasing interest to service providers and systems designers because of the wide bandwidths available for carrying communications at this frequency range. Such wide bandwidths are valuable in supporting applications such as high speed data transmission and video distribution.

Planning for millimeter wave spectrum use must take into account the propagation characteristics of radio signals at this frequency range. While signals at lower frequency bands can propagate for many miles and penetrate more easily through buildings, millimeter wave signals can travel only a few miles or less and do not penetrate solid materials very well. However, these characteristics of millimeter wave propagation are not necessarily disadvantageous. Millimeter waves can permit more densely packed communications links, thus providing very efficient spectrum utilization, and they can increase security of communication transmissions. This paper reviews characteristics of millimeter wave propagation, including free space propagation and the effects of various physical factors on propagation.

FREE SPACE, BENIGN PROPAGATION CONDITIONS

The frequency and distance dependence of the loss between two isotropic antennas is expressed in absolute numbers by the following equation:

$$L_{FSL} = (4\pi R/\lambda)^2 \quad \text{Free Space Loss}$$

where R: distance between transmit and receive antennas; λ: operating wavelength.

After converting to units of frequency and putting in dB form, the equation becomes:

$$L_{FSL\ dB} = 92.4 + 20 \log f + 20 \log R$$

where f: frequency in GHz; R: Line-of-Sight range between antennas in km.

Figure 1 shows the Free Space Loss, or attenuation, incurred for several values of frequency. For every octave change in range, the differential attenuation changes by 6 dB. For example, in going from a 2-kilometer to a 4-kilometer range, the increase in loss is 6 dB. Note that even for short distances, the free space loss can be quite high. This suggests that for applications of millimeter wave spectrum, only short distance communications links will be supported.

MILLIMETER WAVE PROPAGATION LOSS FACTORS

In microwave systems, transmission loss is accounted for principally by the free space loss. However, in the millimeter wave bands additional loss factors come into play, such as gaseous losses and rain in the transmission medium. Factors which affect millimeter wave propagation are given in Figure 2.

Atmospheric Gaseous Losses

Transmission losses occur when millimeter waves traveling through the atmosphere are absorbed by molecules of oxygen, water vapor and other gaseous atmospheric constituents. These losses are greater at certain frequencies, coinciding with the mechanical resonant frequencies of the gas molecules. Figure 3 gives qualitative data on gaseous losses. It shows several peaks that occur due to absorption of the radio signal by water vapor (H_2O) and oxygen (O_2). At these frequencies, absorption results in high attenuation of the radio signal and, therefore, short propagation distance. For current technology the important absorption peaks occur at 24 and 60 GHz. The spectral regions between the absorption peaks provide windows where propagation can more readily occur. The transmission windows are at about 35 GHz, 94 GHz, 140 GHz and 220 GHz.

The H_2O and O_2 resonances have been studied extensively for purposes of predicting millimeter propagation characteristics. Figure 4 [3] shows an expanded plot of the atmospheric absorption versus frequency at altitudes of 4 km and sea level, for water content of 1 gm/m^3 and 7.5 gm/m^3, respectively (the former value represents relatively dry air while the latter value represents 75% humidity for a temperature of 10°C).

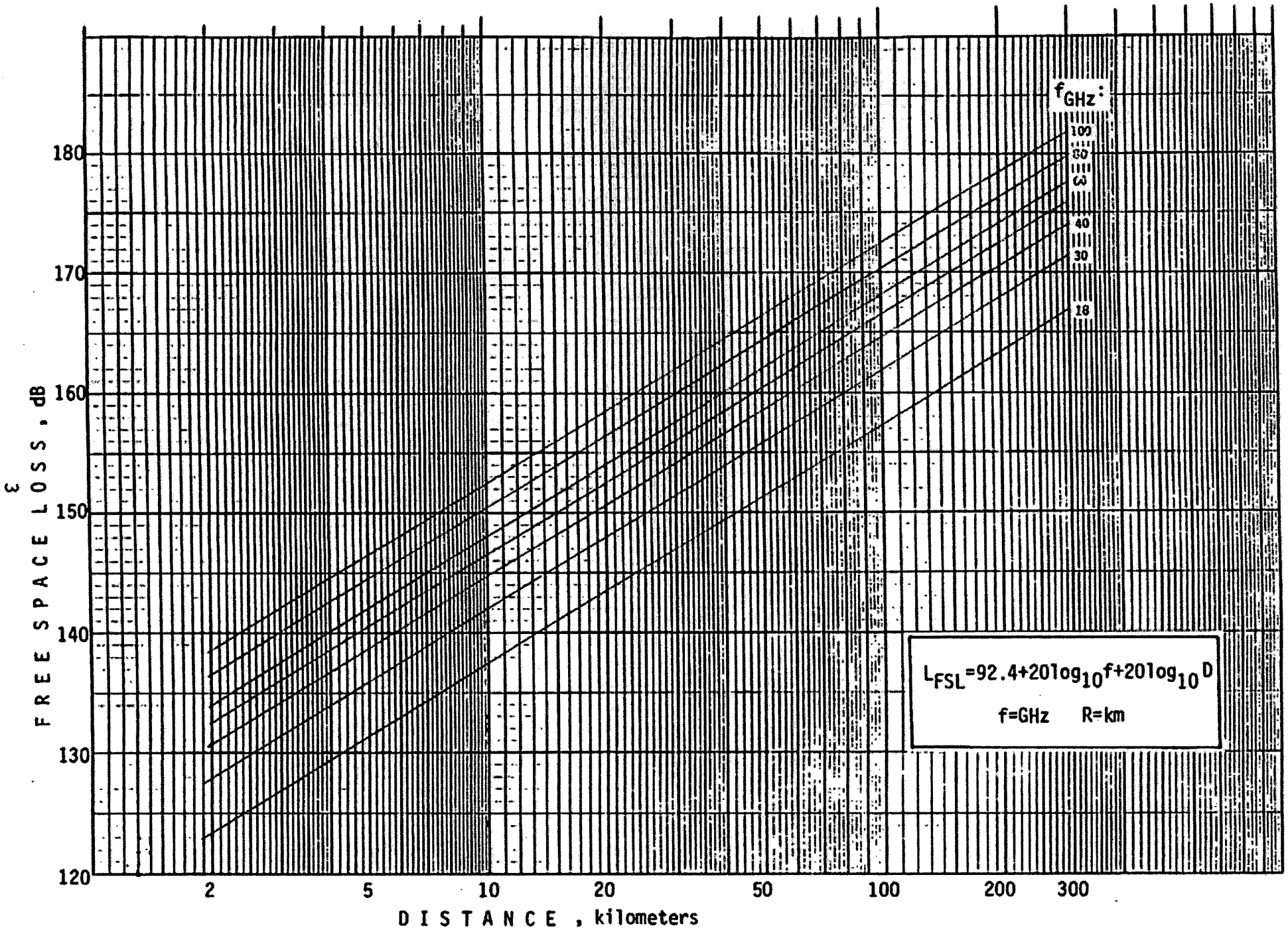
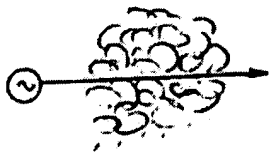


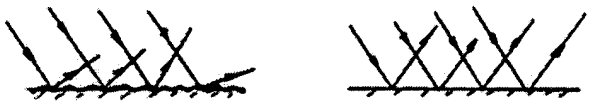
Figure 1: Free Space Loss Between Isotropic Antennas

- ATMOSPHERIC GASES ATTENUATION
  - WATER VAPOR ABSORPTION
  - OXYGEN ABSORPTION
- PRECIPITATION ATTENTUATION
  - RAIN



- FOLIAGE BLOCKAGE
- SCATTERING EFFECTS *
  - DIFFUSED
  - SPECULAR

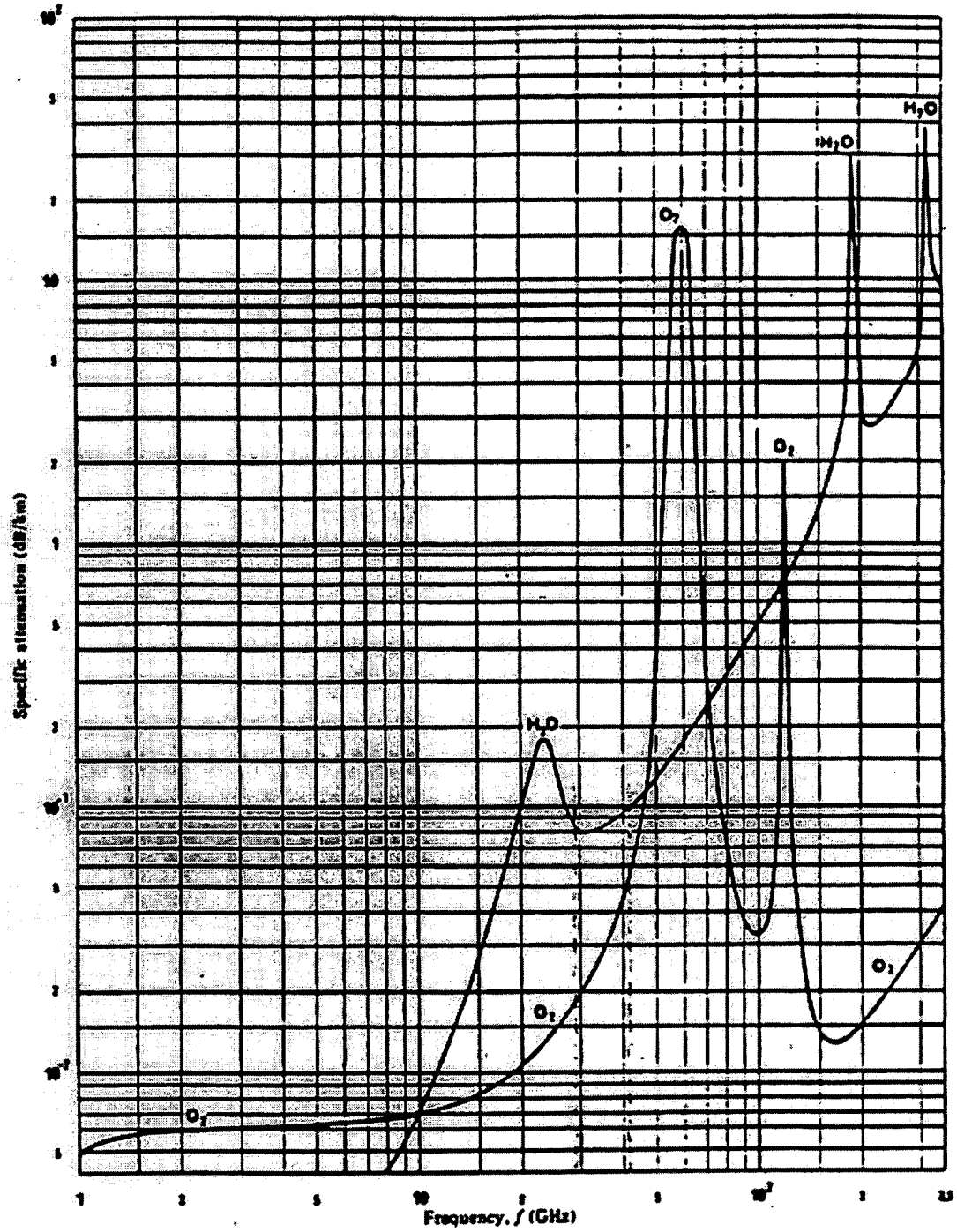
  } REFLECTIONS



- DIFFRACTION (BENDING)

* As frequencies increase, the wavelengths become shorter and the reflective surface appears rougher. This results in more diffused reflection as opposed to specular refelection.

Figure 2: Propagation Effects Influencing Millimeter Wave Propagations.



- Oxygen & water vapor

Pressure: 1013 mb
Temperature: 15 °C
Water vapour: 7.5 gm⁻³

Figure 3: Specific Attenuation Due to Atmospheric Gases.

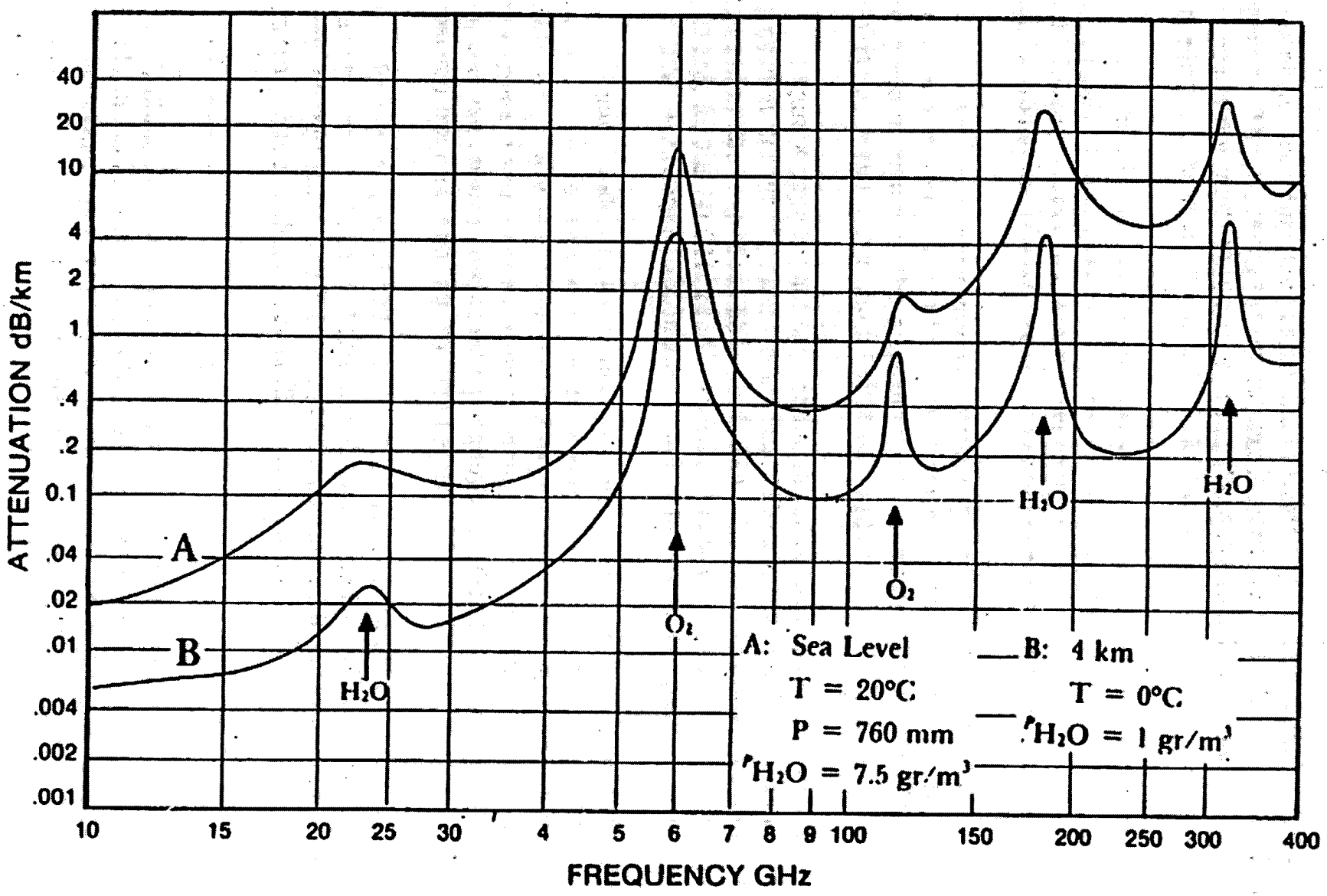


Figure 4: **Average Atmospheric Absorption of Millimeter Waves.**

An additional set of curves for *total* one-way attenuation through the atmosphere, including attenuation due to water vapor and oxygen, is given in Figure 5. This is shown for several angles from the vertical, or zenith. Clearly, the greater this angle Φ, the more atmosphere the signal goes through and, consequently, the more the signal is attenuated.

Figure 6 [1] shows the one-way attenuation through the atmosphere for *oxygen only*. The attenuation increases as the off-zenith angle Φ, increases, due to the longer distance atmospheric penetration. As one would expect, the loss is highest around the 60 GHz oxygen absorption peak for all elevation angles.

Figure 7 shows the gaseous attenuation for oxygen absorption and for water vapor absorption as a function of range, over and above the free-space loss given in Figure 1. The resonances for frequencies below 100 GHz occur at 24 GHz for water vapor and 60 GHz for oxygen.

Figure 8 depicts total attenuation, including free space loss and gaseous attenuation, for three typical frequencies. There is no significant increase in attenuation due to gaseous absorption above the free space loss given in Figure 1, except for the 60 GHz band. Above a distance of about 9 km, the composite loss (FSL + Absorption) increases significantly from free space loss alone.

Figure 9 indicates the frequency reuse possibilities, based on atmospheric gaseous losses, for typical digital fixed service systems operating in the vicinity of 60 GHz. Note that at the 60 GHz oxygen absorption peak, the working range for a typical fixed service communications link is very short, on the order of 2 km, and that another link could be employed on the same frequency if it were separated from the first link by about 4 km.

By contrast, at 55 GHz, the working range for a typical fixed service link is about 5 km, but a second link would have to be located about 18 km away to avoid interference. Other factors must be considered in determining actual frequency reuse such as antenna directivity and intervening obstacle path loss.

Rain Losses

Millimeter wave propagation is also affected by rain. Raindrops are roughly the same size as the radio wavelengths and therefore cause scattering of the radio signal. Figure 10 [1,2] shows the attenuation per kilometer as a function of rain rate. The rain rate in any location in the continental United

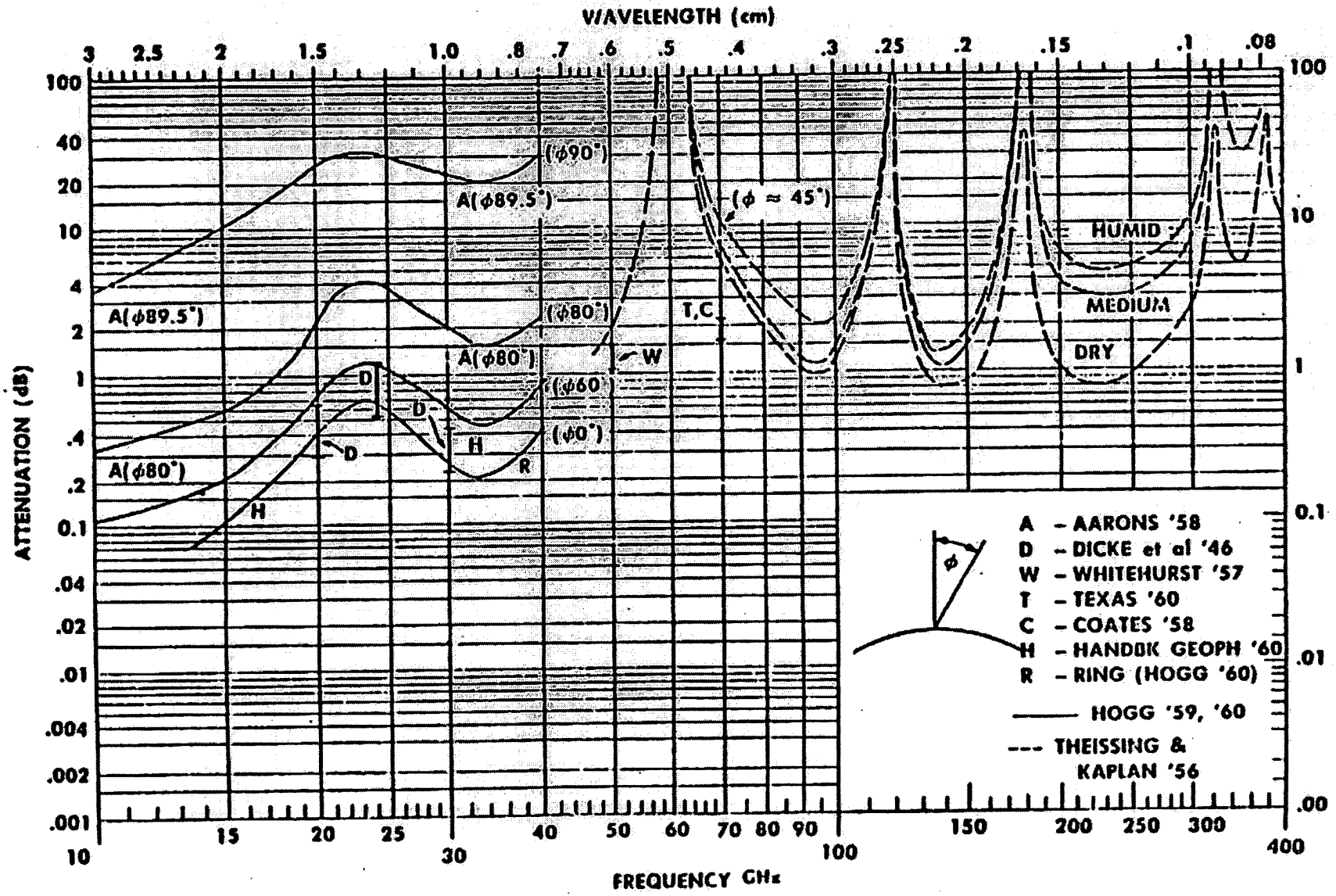


Figure 5 : TOTAL Attenuation for One-Way Transmission Through the Atmospere.

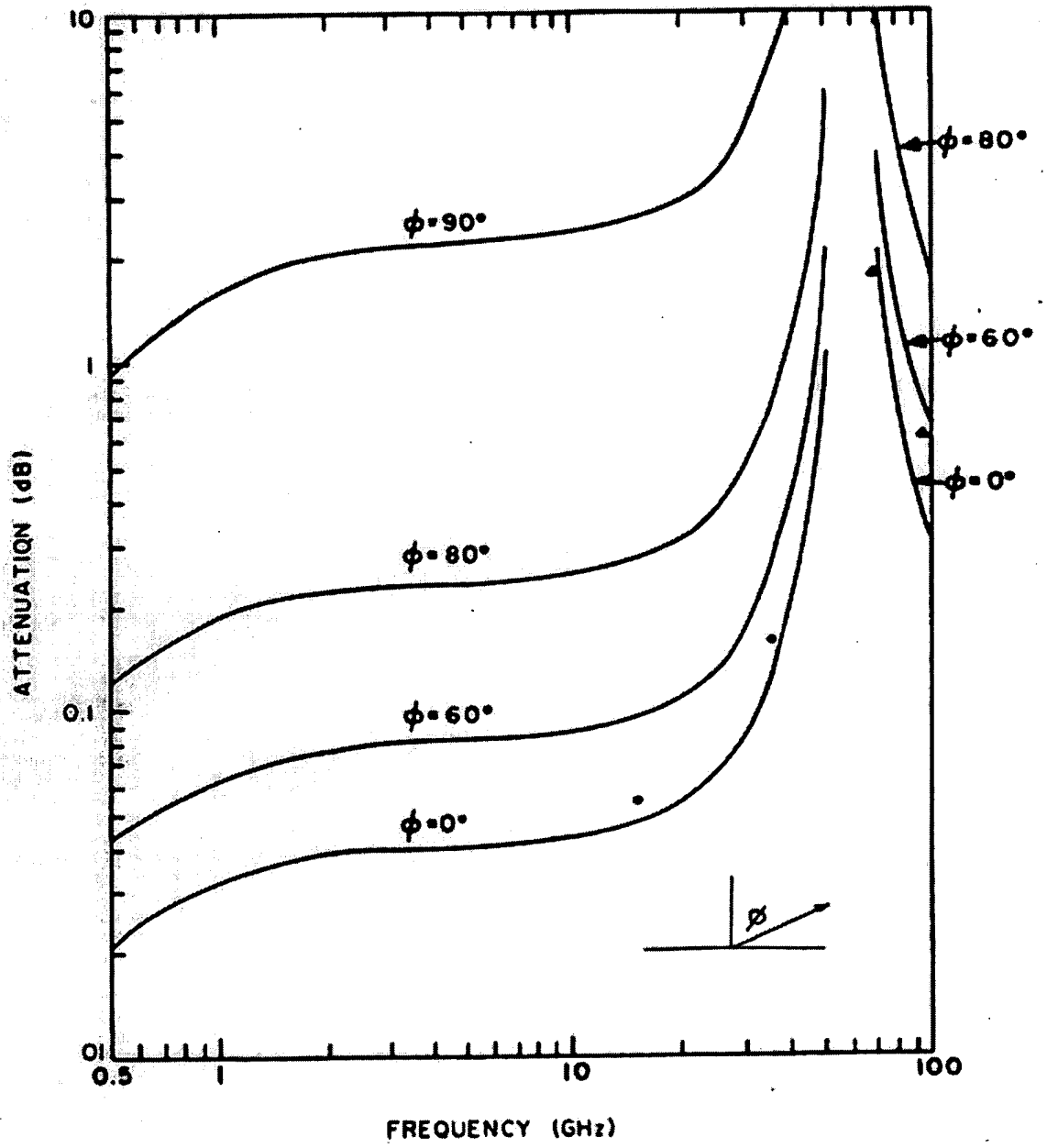


Figure 6: One-Way Attenuation Through the Atmosphere for Oxygen only.

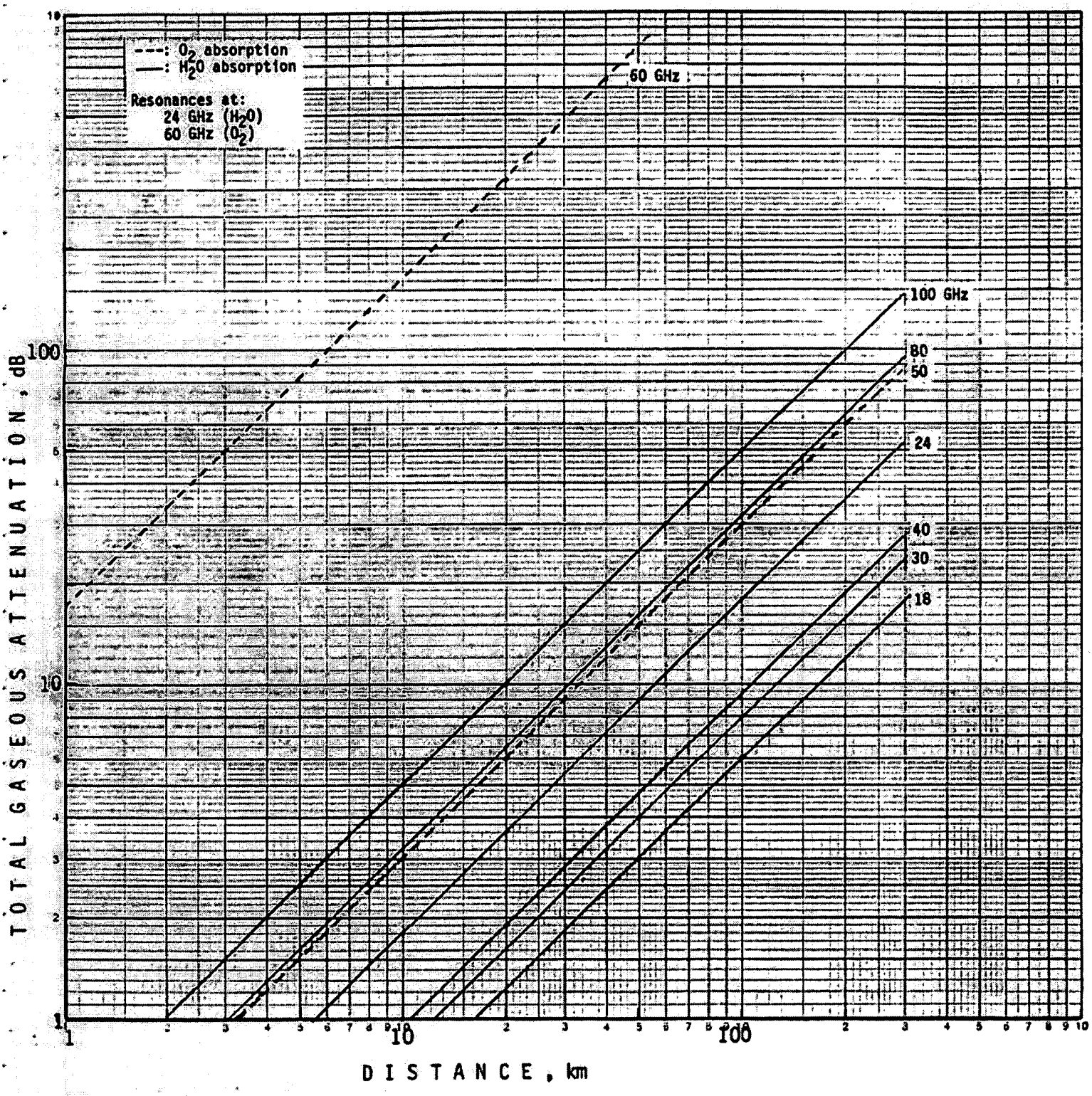


Figure 7 : Gaseous Attenuation Over And Above the Free-Space Loss.

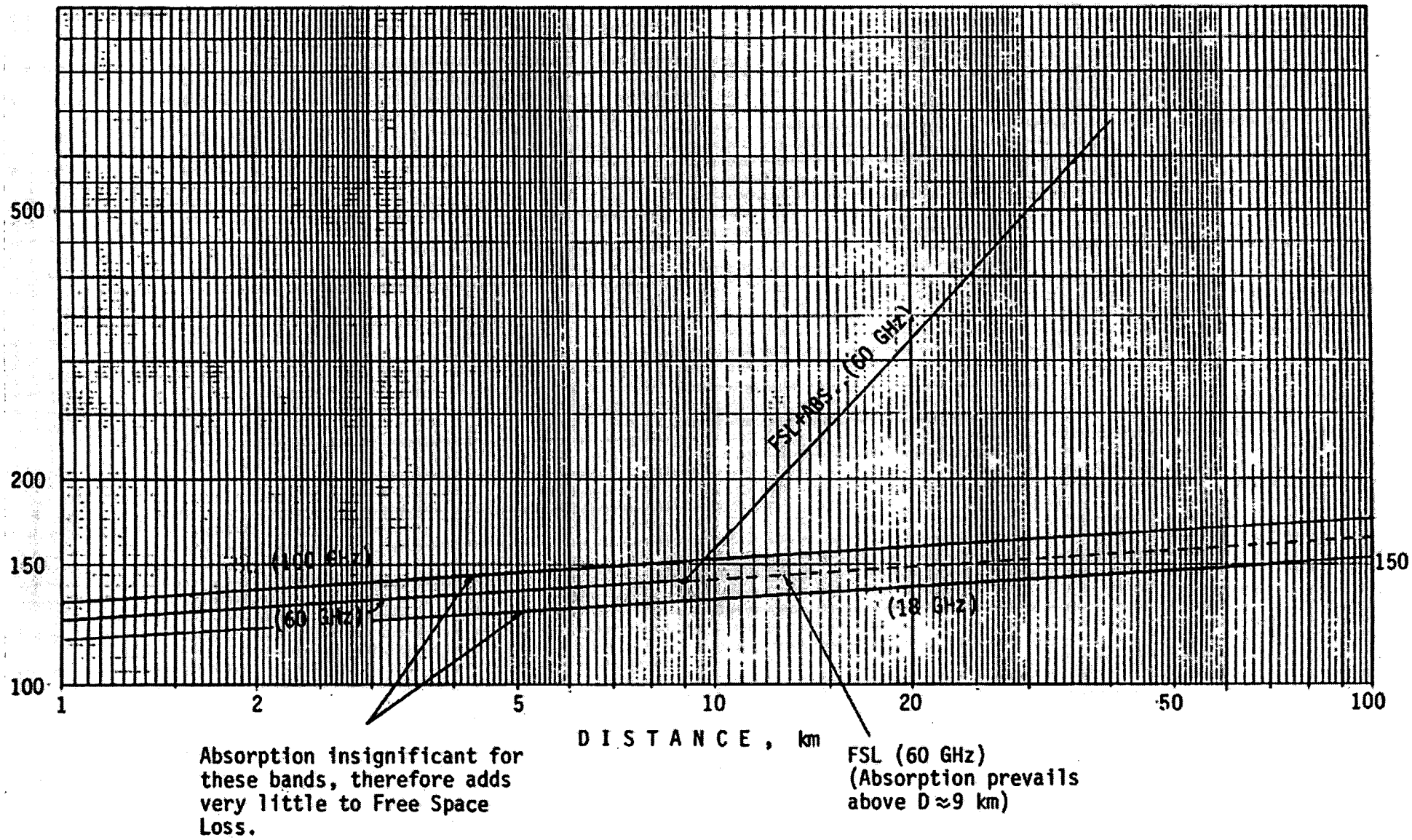
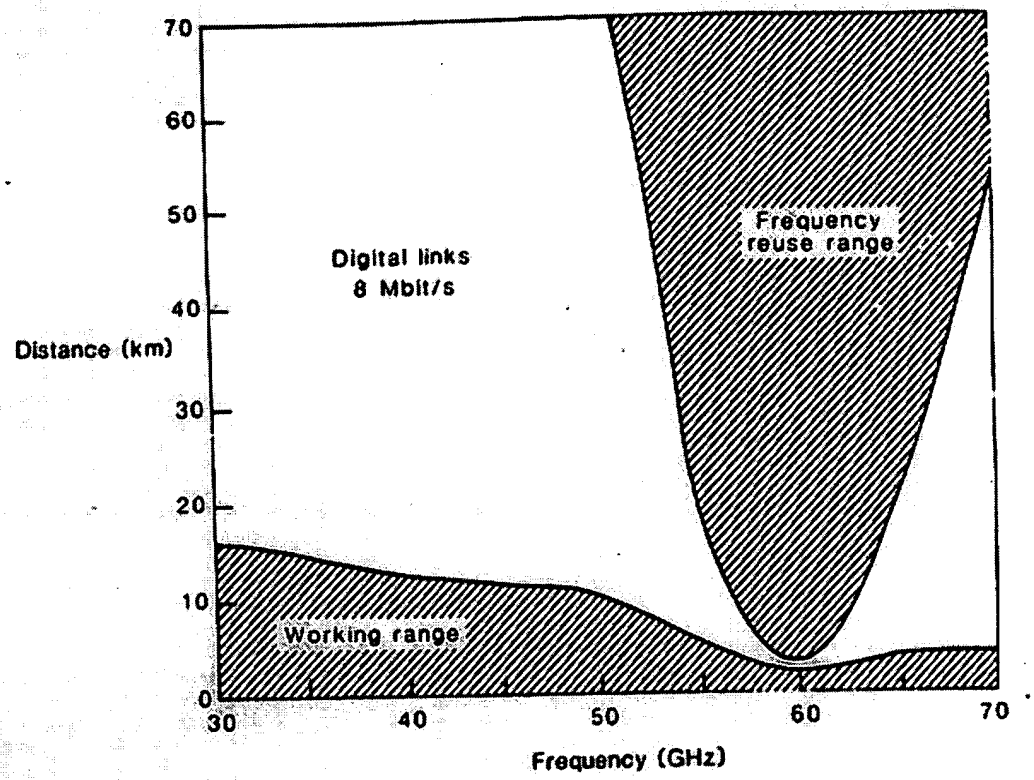


Figure 8: Combination Free Space Loss Plus Absorption.



Note: The potential working range is the average maximum distance over which a typical fixed link can operate. The range is influenced by the attenuation of the radio waves in the intervening space, being shorter in cases of high attenuation. Where two links employ the same frequency (ie frequency re-use), if they are separated by a distance greater than the frequency re-use range, it will be certain that mutual interference will be below an acceptable level. The frequency re-use range is thus always larger than the working range. If the two links are separated by less than the re-use distance, detailed calculations are necessary to determine whether other factors, eg the directionality of the antennas, will provide sufficient protection from mutual interference.

Figure 9: Potential working and frequency re-usage range of millimetric fixed links

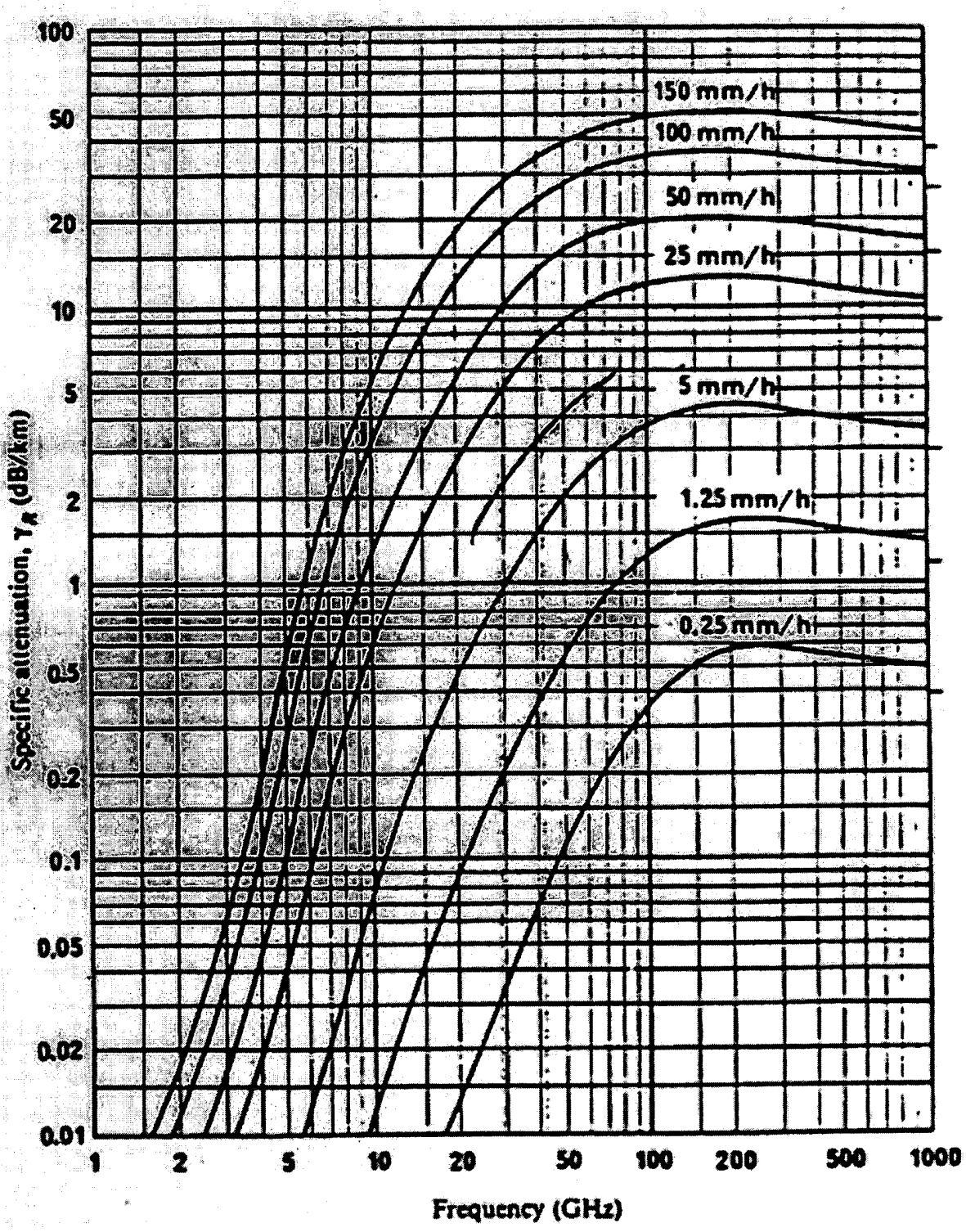


Figure10: Specific Attenuation Due to Rain.

States can be determined by referring to a map of Rain Rate Climate Regions and a chart of associated rainfall statistics, which are shown in Figures 11(a) and 11(b) respectively. For example, from Figure 11(b), for 0.1% of the year (99.9% availability) the rain rate is about 14.5 mm/hour for the sub-region D_2 (Washington region) shown in Figure 11(a).

An increase in the rain factor reduces the communications signal availability. A measure of this availability and the corresponding communications outage is shown in Figure 12. For example,for an availability of 99.99%, the outage is 8.8 hours a year or 1.44 minutes on a 24 hour basis.

Foliage Losses

Foliage losses at millimeter wave frequencies are significant. In fact, the foliage loss may be a limiting propagation impairment in some cases. An empirical relationship has been developed (CCIR Rpt 236-2), which can predict the loss. For the case where the foliage depth is less than 400 meters, the loss is given by

$$L = 0.2\ f^{0.3}\ R^{0.6} \quad \text{dB}$$

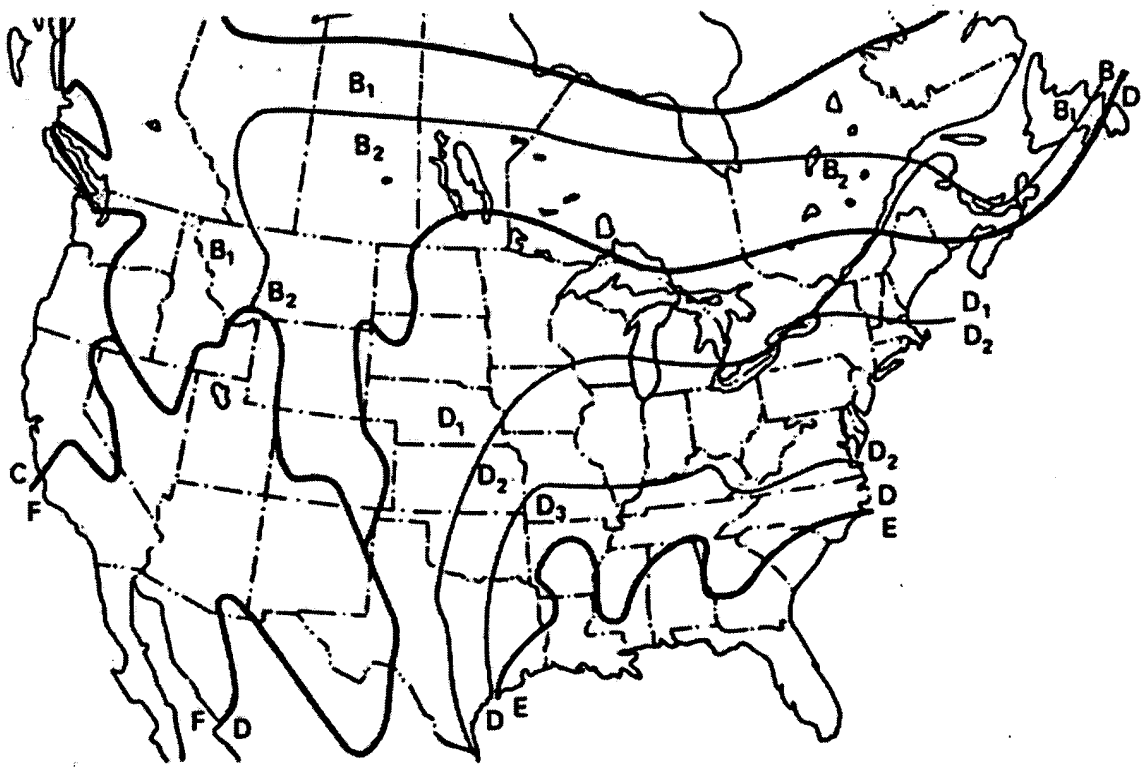
where f: frequency in MHz;

R: depth of foliage transversed in meters,
and applies for R< 400 meters.

This relationship is applicable for frequencies in the range 200-95,000 MHz. For example, the foliage loss at 40 GHz for a penetration of 10 meters (which is about equivalent to a large tree or two in tandem) is about 19 dB. This is clearly not a negligible value.

Scattering/Diffraction

If there is no line-of-sight (LOS) path between the transmitter and the receiver, the signal may still reach the receiver via reflections from objects in proximity to the receiver, or via diffraction or bending. The short wavelengths of millimeter wave signals result in low diffraction. Like light waves, the signals are subject more to shadowing and reflection. (Shadowing makes it easier to shield against unwanted signals in communications systems.) Normally, for non-LOS, the greatest contribution at the receiver is reflected power.



(a) Rain Rate Regions for Conterminous United States and Southern Canada.

Percent of Year	RAIN CLIMATE REGION												Minutes per Year	Hours per Year
	A	B_1	B	B_2	C	D_1	D=D_2	D_3	E	F	G	H		
0.001	28.5	45	57.5	70	78	90	108	126	165	66	185	253	5.26	0.09
0.002	21	34	44	54	62	72	89	106	144	51	157	220.5	10.5	0.18
0.005	13.5	22	28.5	35	41	50	64.5	80.5	118	34	120.5	178	26.3	0.44
0.01	10.0	15.5	19.5	23.5	28	35.5	49	63	98	23	94	147	52.6	0.88
0.02	7.0	11.0	13.5	16	18	24	35	48	78	15	72	119	105	1.75
0.05	4.0	6.4	8.0	9.5	11	14.5	22	32	52	8.3	47	86.5	263	4.38
0.1	2.5	4.2	5.2	6.1	7.2	9.8	14.5	22	35	5.2	32	64	526	8.77
0.2	1.5	2.8	3.4	4.0	4.8	6.4	9.5	14.5	21	3.1	21.8	43.5	1052	17.5
0.5	0.7	1.5	1.9	2.3	2.7	3.6	5.2	7.8	10.6	1.4	12.2	22.5	2630	43.8
1.0	0.4	1.0	1.3	1.5	1.8	2.2	3.0	4.7	6.0	0.7	8.0	12.0	5260	87.7
2.0	0.1	0.5	0.7	0.8	1.1	1.2	1.5	1.9	2.9	0.2	5.0	5.2	10520	175
5.0	0.0	0.2	0.3	0.3	0.5	0.0	0.0	0.0	0.5	0.0	1.8	1.2	26298	438

(b) Point Rain Rate Distribution Values (mm/hr) Versus Percent of Year Rain Rate is Exceeded.

Figure 11: Rain Rates in the United States and Canada.

Availability %	Outage/Year	Time Per Month (Avg)	Time Per Day (Avg)
50	4380 hrs	360 hrs	12 hrs
70	2628 hrs	216 hrs	7.2 hrs
80	1752 hrs	144 hrs	4.8 hrs
90	876 hrs	72 hrs	2.4 hrs
95	438 hrs	36 hrs	1.2 hrs
98	175 hrs	14 hrs	29 min
99	88 hrs	7 hrs	14.4 min
99.5	43.8 hrs	3.6 hrs	7.2 min
99.9	8.8 hrs	43 min	1.44 min
99.99 *	53 min	4.3 min	8.5 sec
99.999	5.3 min	26 sec	0.86 sec
99.9999	32 sec	2.6 sec	0.086 sec

*e.g. : One year has 8760 hours, or 8760 x 60 minutes.

For link availability of 99.99 %:

Unavailability is 1-0.9999 = 0.0001 (outage) , outage(%)=1-availability

or .0001 x 8760 x 60 = 52.56 minutes

Does not necessarily imply that there is a complete loss of signal, but signal may be present at reduced quality.

Figure 12: Relationship Between System Availability and Outage Time.#

Reflections and the associated amount of signal diffusion are strongly dependent on the reflectivity of the reflecting material. Shorter wavelengths (higher frequencies) cause the reflecting material to appear relatively "rougher," which results in greater diffusion of the signal and less specular (*i.e.*, direct) reflection. Diffusion provides less power at the receiver than specular reflected power.

SKY NOISE (BRIGHTNESS TEMPERATURE) IN MILLIMETER BANDS

Anything that absorbs electromagnetic energy is also a radiator. Constituents of the atmosphere that cause attenuation, such as water vapor, oxygen and rain, radiate signals which are noise-like. When these signals impinge on a receiver antenna, they degrade system performance.

An earth station antenna aimed at a satellite at a high elevation angle will pick up sky noise emanating from atmospheric constituents (and other sources). This is referred to as the sky noise temperature or brightness temperature. For low elevation angles, the dominant noise will be mostly from terrain and will be picked up by the antenna sidelobes.

Figures 13 and 14 [5] show the sky noise temperature as a function of frequency. The sky noise peaks at the millimeter wave gaseous molecule resonance bands; and this phenomenon also affects the suitability of millimeter wave spectrum region for communications applications.

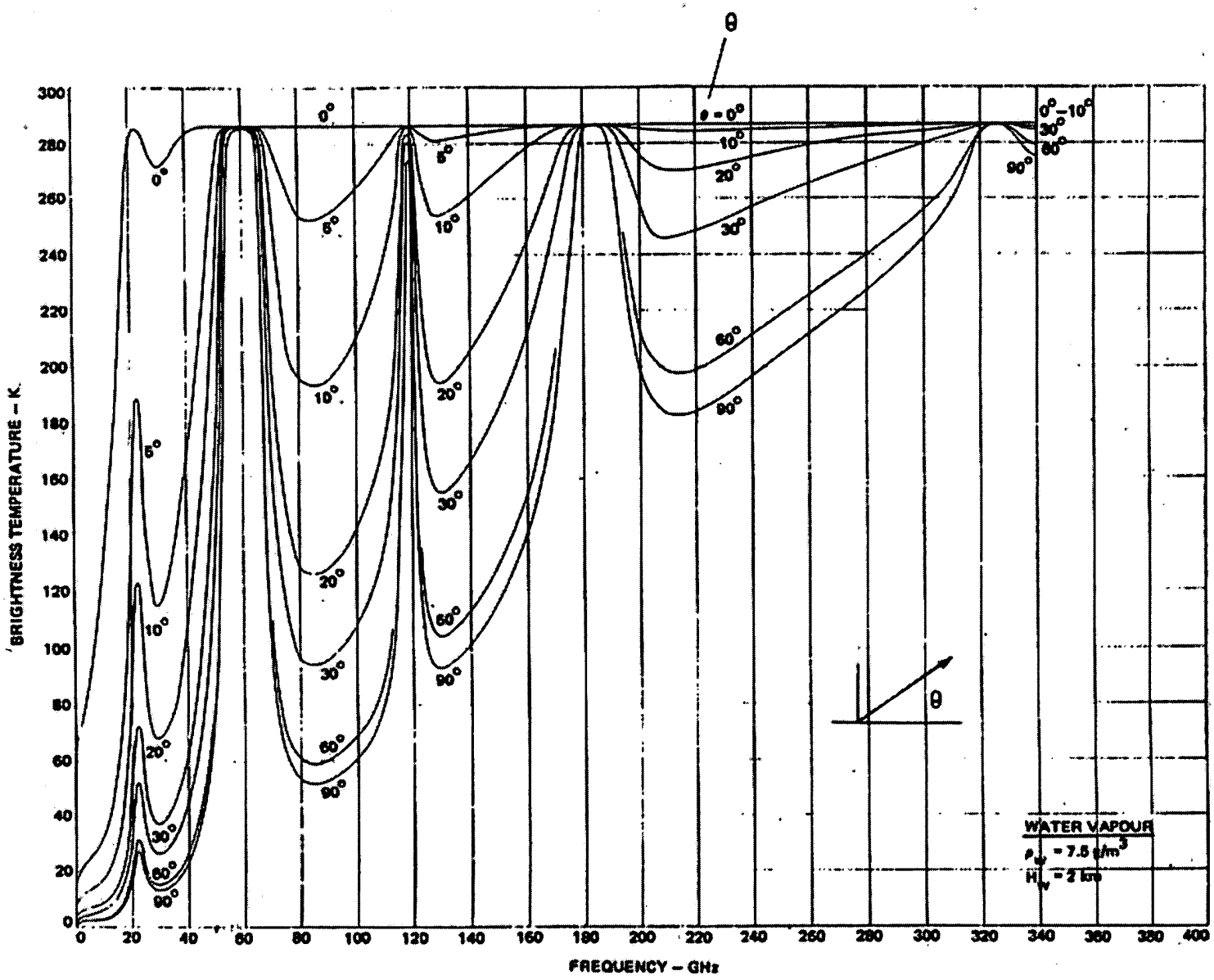
The noise entering a receiver from the antenna is commonly referred to as the antenna noise temperature and it includes components of sky noise. The antenna noise temperature adds to the receiver noise temperature to form the system noise temperature:

$$T_s = T_{ANT} + T_{RCVR}$$

(To be strictly correct the system noise temperature stems from several sources, which are depicted in Figure 15.)

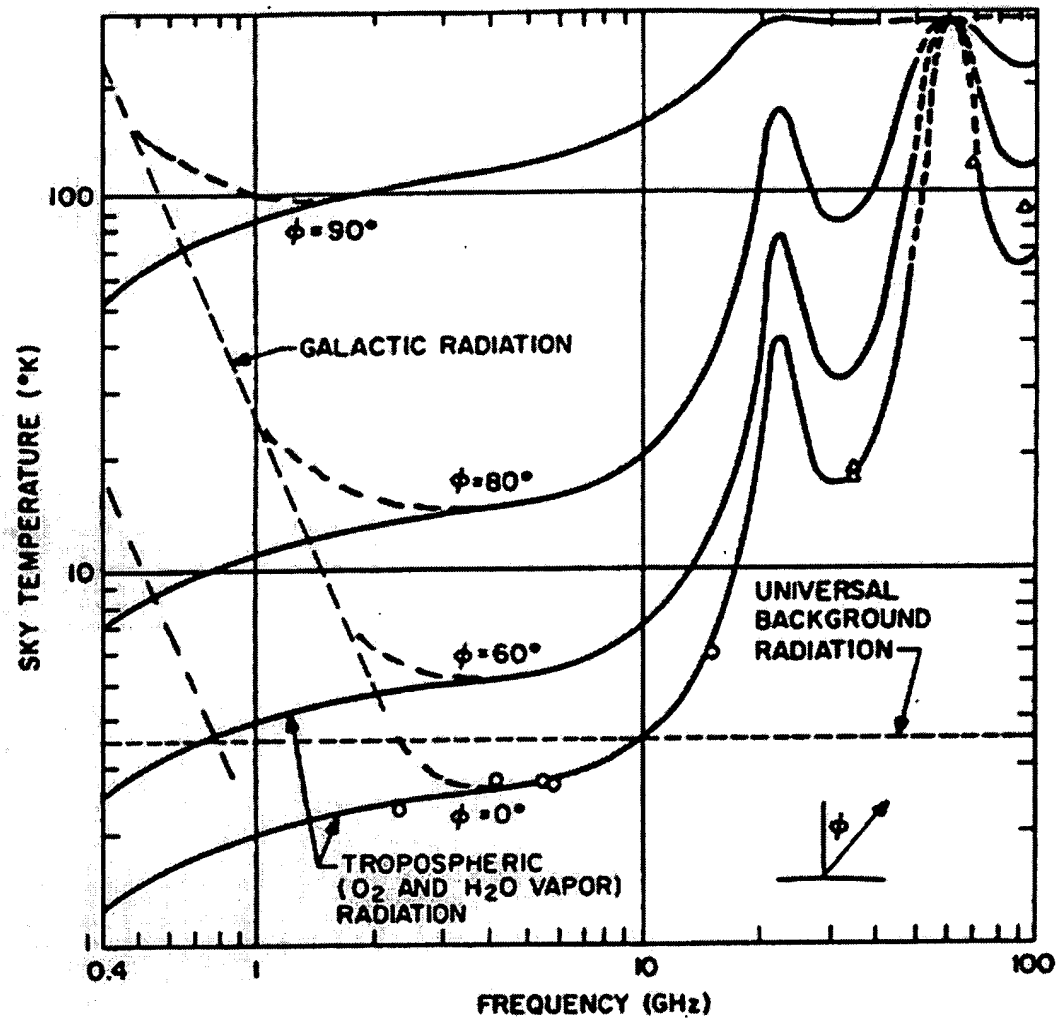
MILLIMETER WAVE APPLICATIONS

Communication systems operating at millimeter wave frequencies can take advantage of the propagation effects described in the preceding sections. For



- θ: Elevation angle; for θ=0° the path is essentially terrestrial.

Figure 13: Brightness Temperature (clear air) for a Water Vapor Concentration Concentration of 7.5g/m^3, for frequency ranges 1 to 350 GHz.



Sky Temperature (0_2 and H_20)

Figure 14: Sky Temperature Verus Frequency for Various Antenna Beam Pointing Angles From Zenith.

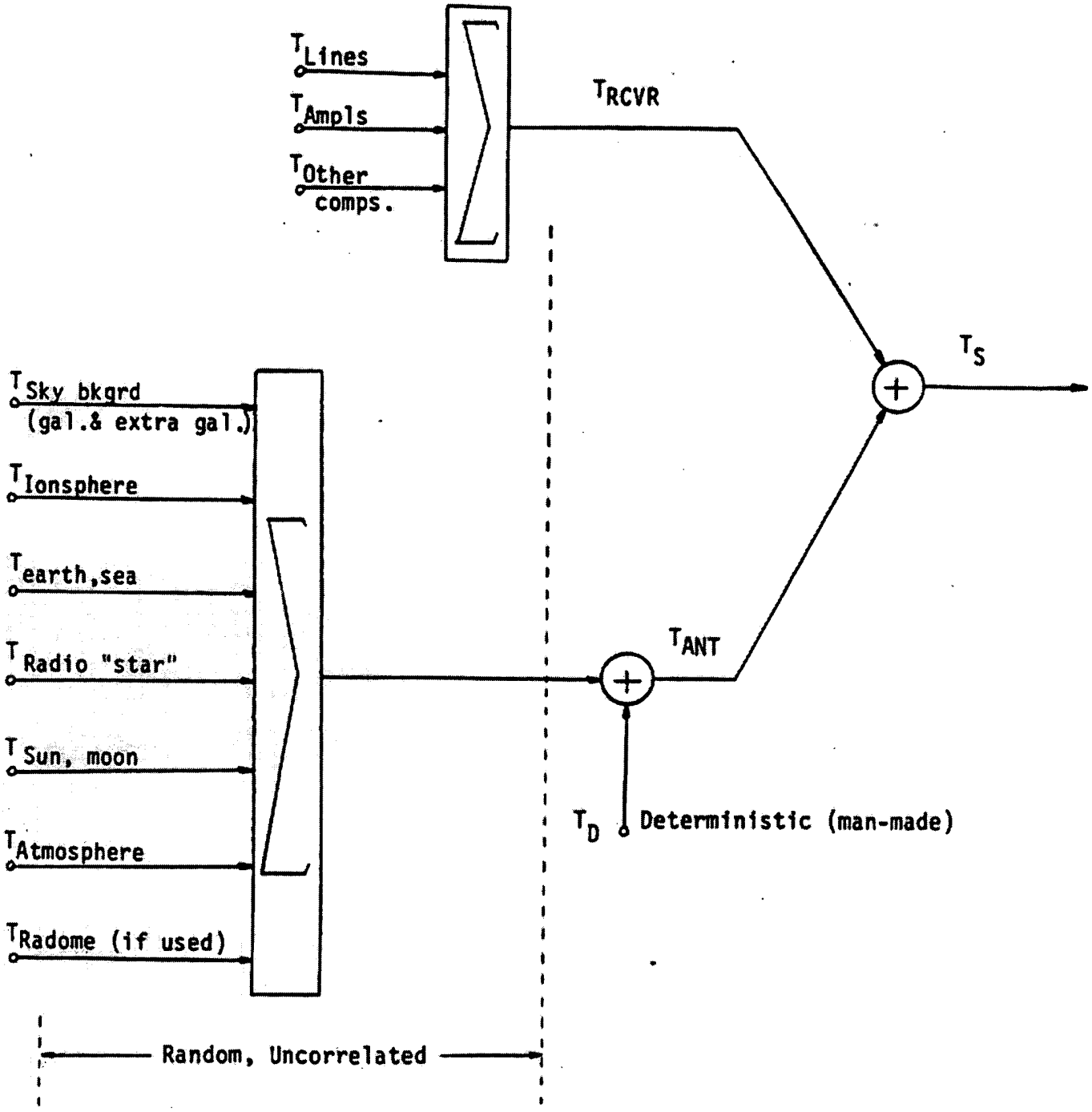


Figure 15 : Model Depicting Contributors to the System Noise Temperature

example [7]:

- o Propagation ideally suits short range (<20 km) communications;
- o Limited range permits a high degree of frequency reuse;
- o In the absorption resonance bands, relatively secure communications can be performed.

On the other hand, propagation effects impose restrictions:

- o High attenuation in a rain environment;
- o Limited communications range, typically <20 km.;
- o Poor foliage penetration.

System designers can take advantage of the propagation properties manifested at millimeter wave frequencies to develop radio service applications. The windows in the spectrum are particularly applicable for systems requiring all weather/night operation, such as vehicular radar systems; or for short range point-to-point systems such as local area networks. The absorption bands (*e.g.*, 60 GHz) would be applicable for high data rate systems where secure communications with low probability of intercept is desirable; for services with a potentially high density of transmitters operating in proximity; or for applications where unlicensed operations are desirable.

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[2]. L.J. Ippolito, "Propagation Effects Handbook for Satellite Systems Design," *NASA Doc. 1082(4)*, Feb. 1989, ch. 3 and 6 *passim.*

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FREQUENCY BAND DESIGNATIONS

Q : 33-50 GHz

U : 40-60 GHz

V : 50-75 GHz

E : 60-90 GHz

W : 75-110 GHz

F : 90-170 GHz

D : 110-170 GHz

G : 140-220 GHz

GLOSSARY OF TERMS

DIFFRACTION: Change in direction (bending) of propagating energy around an object cause by interference between the radiated energy and induced current in the object. There is no line of sight between the transmitter and receiver.

FREE SPACE LOSS: The amount of attenuation of RF energy on an unobstructed path between isotropic antennas. Basically, dilution of energy as the RF propagates away from a source.

ISOTROPIC ANTENNA: An antenna which radiates in all directions (about a point) with a gain of unity (not a realizable antenna, but a useful concept in antenna theory).

REFRACTION: Change in direction of propagating radio energy caused by a change in the refractive index, or density, of a medium.

RESONANT ENERGY: Frequencies in the band where attenuation peaks. In contrast to windows, where the attenuation bottoms out and is lower.

LEXSEE 814 F.2D 628

Verdegaal Brothers, Inc., William Verdegaal, George Verdegaal, Appellees, v. Union Oil Company of California, BREA Agricultural Services, Inc., Appellants

No. 86-1258

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

814 F.2d 628; 1987 U.S. App. LEXIS 175; 2 U.S.P.Q.2D (BNA) 1051

March 12, 1987, Decided

PRIOR HISTORY: [**1]

Appealed from U.S. District Court for the Eastern District of California, Judge Coyle.

DISPOSITION:

Reversed.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant oil company sought review of a decision of the U.S. District Court for the Eastern District of California denying appellant's motion for judgment notwithstanding the verdict and finding appellee corporation's fertilizer patent valid and infringed under *35 U.S.C.S. § § 102,* 103.

OVERVIEW: Appellee corporation sued appellant oil company, claiming that appellant violated appellee's fertilizer patent. After the trial court ruled that appellee's patent was valid and infringed, appellant sought review. On appeal, the court said that clear and convincing evidence was required, and the evidence was sufficient that reasonable jurors could only conclude that the patent was valid. The court reversed the trial court's denial of appellant's motion for judgment notwithstanding the verdict because of the lack of clear and convincing evidence and because the jury verdict was unsupported by substantial evidence and could not stand.

OUTCOME: The court reversed denial of appellant's motion for judgment notwithstanding the verdict because the jury's verdict of validity was unsupported by substantial evidence and could not stand.

LexisNexis(R) Headnotes

Civil Procedure > Trials > Judgment as Matter of Law
[HN1] When considering a motion for judgment notwithstanding the verdict (JNOV) a district court must: (1) consider all of the evidence; (2) in a light most favorable to the non-moving party; (3) drawing all reasonable inferences favorable to that party; (4) without determining credibility of the witnesses; and (5) without substituting its choice for that of the jury's in deciding between conflicting elements of the evidence. A district court should grant a motion for JNOV only when it is convinced upon the record before the jury that reasonable persons could not have reached a verdict for the nonmoving party.

Civil Procedure > Trials > Judgment as Matter of Law
[HN2] To reverse the district court's denial of the motion for judgment notwithstanding the verdict, the movant must convince the court that either the jury's factual findings are not supported by substantial evidence, or, if they are, that those findings cannot support the legal conclusions which necessarily were drawn by the jury in forming its verdict. Substantial evidence is more than just a mere scintilla; it is such relevant evidence from the record taken as a whole as a reasonable mind might accept as adequate to support the finding under review.

Civil Procedure > Trials > Judgment as Matter of Law
[HN3] A trial court's denial of a motion for judgment notwithstanding the verdict must stand unless the evidence is of such quality and weight that reasonable and fair-minded persons in the exercise of impartial judgment could not reasonably return the jury's verdict.

Patent Law > Inequitable Conduct > General Overview
Patent Law > Infringement Actions > Burdens of Proof
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
[HN4] The presumption of validity afforded a U.S. patent by *35 U.S.C.S. § 282* requires that the party challenging validity prove the facts establishing invalidity by clear and convincing evidence.

Patent Law > Anticipation & Novelty > General Overview
[HN5] A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

Patent Law > Originality > Joint & Sole Inventorship
[HN6] See *35 U.S.C.S. § 102*(e).

COUNSEL:

Andrew J. Belansky, Christie, Parker & Hale, argued for Appellants. With him on the brief was David A. Dillard.

John P. Sutton, Limbach, Limbach & Sutton, argued for Appellee. With him on the brief was Michael E. Dergosits.

JUDGES:

Markey, Chief Judge, and Davis and Nies, Circuit Judges.

OPINION:

[*630] NIES, Circuit Judge.

Union Oil Company of California and Brea Agricultural Services, Inc. (collectively Union Oil) appeal from a judgment of the United States District Court for the Eastern District of California, No. CV-F-83-68 REC, entered on a jury verdict which declared U.S. Patent No. *4,310,343* (*'343*), owned by Verdegaal Brothers, Inc., "valid" and claims 1, 2, and 4 thereof infringed by Union Oil. Union Oil's motion for judgment notwithstanding the verdict (JNOV) was denied. We reverse.

I

BACKGROUND

The General Technology

The patent in suit relates to a process for making certain known urea-sulfuric acid liquid fertilizer products. These products are made by reacting water, urea (a nitrogen-containing chemical), and sulfuric acid (a sulfur-containing [**2] chemical) in particular proportions. The nomenclature commonly used by the fertilizer industry refers to these fertilizer products numerically according to the percentages by weight of four fertilizer constituents in the following order: nitrogen, phosphorous, potassium, and sulfur. Thus, for example, a fertilizer containing 28% nitrogen, no phosphorous or potassium, and 9% sulfur is expressed numerically as 28-0-0-9.

The Process of the '343 Patent

The process disclosed in the *'343* patent involves the chemical reaction between urea and sulfuric acid, which is referred to as an exothermic reaction because it gives off heat. To prevent high temperature buildup, the reaction is conducted in the presence of a nonreactive, nutritive heat sink which will absorb the heat of reaction. Specifically, a previously-made batch of liquid fertilizer -- known as a "heel" -- can serve as the heat sink to which more reactants are added. Claims 1 and 2 are representative:

> 1. In a process for making a concentrated liquid fertilizer by reacting sulfuric acid and urea, to form an end product, the improvement comprising:
>
> > a. providing a non-reactive, nutritive heat sink, capable [**3] of dissipating the heat of urea and sulfuric acid, in an amount at least 5% of the end product,
> > b. adding water to the heat sink in an amount not greater than 15% of the end product,
> > c. adding urea to the mixture in an amount of at least 50% of the total weight of the end product,
> > d. adding concentrated sulfuric acid in an amount equal to at least 10% of the total weight of the end product.
>
> 2. The process of claim 1 wherein the heat sink is recycled liquid fertilizer.

Procedural History

Verdegaal brought suit against Union Oil in the United States District Court for the Eastern District of California charging that certain processes employed by Union Oil for making liquid fertilizer products infringed all claims of its *'343* patent. Union Oil defended on the grounds of noninfringement and patent invalidity under *35 U.S.C. § § 102,* 103. The action was tried before a jury which returned a verdict consisting of answers to five questions. Pertinent here are its answers that the *'343* patent was "valid" over the prior art, and that certain of Union Oil's processes infringed claims 1, 2, and 4 of the patent. None were found to infringe [**4] claims 3 or 5. Based on the jury's verdict, the district court entered judgment in favor of Verdegaal.

Having unsuccessfully moved for a directed verdict under *Fed. R. Civ. P. 50(a)*, Union Oil timely filed a motion under Rule 50(b) for JNOV seeking a judgment that the claims of the *'343* patent were invalid [*631] under sections 102 and 103. The district court denied the motion without opinion.

II

ISSUE PRESENTED

Did the district court err in denying Union Oil's motion for JNOV with respect to the validity of claims 1, 2, and 4 of the *'343* patent?

III

Standard of Review

[HN1] When considering a motion for JNOV a district court must: (1) consider all of the evidence; (2) in a light most favorable to the non-moving party; (3) drawing all reasonable inferences favorable to that party; (4) without determining credibility of the witnesses; and (5) without substituting its choice for that of the jury's in deciding between conflicting elements of the evidence. *Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1512-13, 220 U.S.P.Q. (BNA) 929, 936* (Fed. Cir. [**5]), *cert. denied, 469 U.S. 871, 83 L. Ed. 2d 150, 105 S. Ct. 220, 224 U.S.P.Q. (BNA) 520 (1984); Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1546, 220 U.S.P.Q. (BNA) 193, 197 (Fed. Cir. 1983).* A district court should grant a motion for JNOV only when it is convinced upon the record before the jury that reasonable persons could not have reached a verdict for the nonmoving party. *Railroad Dynamics, 727 F.2d at 1513, 220 U.S.P.Q. (BNA) at 936; Connell, 722 F.2d at 1546, 220 U.S.P.Q. (BNA) at 197.*

[HN2] To reverse the district court's denial of the motion for JNOV, Union Oil must convince us that either the jury's factual findings are not supported by substantial evidence, or, if they are, that those findings cannot support the legal conclusions which necessarily were drawn by the jury in forming its verdict. *See Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 893, 221 U.S.P.Q. (BNA) 669, 673* (Fed. Cir.), *cert. denied, 469 U.S. 857, 83 L. Ed. 2d 120, 105 S. Ct. 187 (1984), Railroad Dynamics, 727 F.2d at 1512, 220 U.S.P.Q. (BNA) at 936.* [**6] Substantial evidence is more than just a mere scintilla; it is such relevant evidence from the record taken as a whole as a reasonable mind might accept as adequate to support the finding under review. *Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229, 83 L. Ed. 126, 59 S. Ct. 206 (1938); Perkin-Elmer, 732 F.2d at 893, 221 U.S.P.Q. (BNA) at 673; SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n, 718 F.2d 365, 371 n.10, 218 U.S.P.Q. (BNA) 678, 684 n.10 (Fed. Cir. 1983).* [HN3] A trial court's denial of a motion for JNOV must stand unless the evidence is of such quality and weight that reasonable and fair-minded persons in the exercise of impartial judgment could not reasonably return the jury's verdict. *Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 758, 221 U.S.P.Q. (BNA) 473, 477 (Fed. Cir. 1984).*

Our precedent holds that [HN4] the presumption of validity afforded a U.S. patent by *35 U.S.C. § 282* requires that the [**7] party challenging validity prove the facts establishing invalidity by clear and convincing evidence. *American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360, 220 U.S.P.Q. (BNA) 763, 770* (Fed. Cir.), *cert. denied, 469 U.S. 821, 83 L. Ed. 2d 41, 105 S. Ct. 95 (1984).* Thus, the precise question to be resolved in this case is whether Union Oil's evidence is so clear and convincing that reasonable jurors could only conclude that the claims in issue were invalid. *See Perkin-Elmer, 732 F.2d at 893, 221 U.S.P.Q. (BNA) at 673; Railroad Dynamics, 727 F.2d at 1511, 220 U.S.P.Q. (BNA) at 935.*

Anticipation

[HN5] A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *See, e.g., Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 715, 223 U.S.P.Q. (BNA) 1264, 1270 (Fed. Cir. 1984); Connell, 722 F.2d at 1548, 220 U.S.P.Q. (BNA) at 198; Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771, 218 U.S.P.Q. (BNA) 781, 789 (Fed. Cir. 1983),* [**8] *cert. denied, 465 U.S. 1026, 79 L. Ed. 2d 687, 104 S. Ct. 1284, 224 U.S.P.Q. (BNA) 520 (1984).* Union Oil asserts that the subject claims of the *'343* patent [*632] are anticipated under *35 U.S.C. § 102*(e) n1 by the teachings found in the original application for U.S. Patent No. *4,315,763* to Stoller, which the jury was instructed was prior art.

n1 Section 102(e) provides:

> [HN6] A person shall be entitled to a patent unless -- . . .
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
> . . .

From the jury's verdict of patent validity, we must presume [**9] that the jury concluded that Union Oil failed to prove by clear and convincing evidence that claims 1, 2, and 4 were anticipated by the Stoller patent. *See Perkin-Elmer, 732 F.2d at 893, 221 U.S.P.Q. (BNA) at 673; Railroad Dynamics, 727 F.2d at 1516, 220 U.S.P.Q. (BNA) at 939.* Under the instructions of this case, this conclusion could have been reached only if the jury found that the Stoller patent did not disclose each and every element of the claimed inventions. Having reviewed the evidence, we conclude that substantial evidence does not support the jury's verdict, and, therefore, Union Oil's motion for JNOV on the grounds that the claims were anticipated should have been granted.

The Stoller patent discloses processes for making both urea-phosphoric acid and urea-sulfuric acid fertilizers. Example 8 of Stoller specifically details a process for making 30-0-0-10 urea-sulfuric acid products. There is no dispute that Example 8 meets elements b, c, and d of claim 1, specifically the steps of adding water in an amount not greater than 15% of the product, urea in an amount of at least 50% of the product, and concentrated sulfuric acid in an amount [**10] of at least 10% of the product. Verdegaal disputes that Stoller teaches element a, the step of claim 1 of "providing a non-reactive, nutritive heat sink." As set forth in claim 2, the heat sink is recycled fertilizer. n2

> n2 Claim 4 is written in terms of approximate percentages of all reactants by weight of the end product. No argument is made that the process of claim 4 would result in a fertilizer product any different from that disclosed by Example 8 of Stoller.

The Stoller specification, beginning at column 7, line 30, discloses:

> Once a batch of liquid product has been made, it can be used as a base for further manufacture. This is done by placing the liquid in a stirred vessel of appropriate size, adding urea in sufficient quantity to double the size of the finished batch, adding any water required for the formulation, and slowly adding the sulfuric acid while stirring. Leaving a heel of liquid in the vessel permits further manufacture to be conducted in a stirred fluid mass.

This portion [**11] of the Stoller specification explicitly teaches that urea and sulfuric acid can be added to recycled fertilizer, i.e., a heel or base of previously-made product. Dr. Young, Union Oil's expert, so testified. Verdegaal presented no evidence to the contrary.

Verdegaal first argues that Stoller does not anticipate because in Stoller's method sulfuric acid is added *slowly*, whereas the claimed process allows for rapid addition. However, there is no limitation in the subject claims with respect to the rate at which sulfuric acid is added, and, therefore, it is inappropriate for Verdegaal to rely on that distinction. *See SSIH, 718 F.2d at 378, 218 U.S.P.Q. (BNA) at 689.* It must be assumed that slow addition would not change the claimed process in any respect including the function of the recycled material as a heat sink.

Verdegaal next argues that the testimony of Union Oil's experts with respect to what Stoller teaches could well have been discounted by the jury for bias. Discarding that testimony does not eliminate the reference itself as evidence or its uncontradicted disclosure that a base of recycled fertilizer in a process may be used to make more of the product. [**12]

Verdegaal raises several variations of an argument, all of which focus on the [*633] failure of Stoller to explicitly identify the heel in his process as a "heat sink." In essence, Verdegaal maintains that because Stoller did not recognize the "inventive concept" that the heel functioned as a heat sink, Stoller's process cannot anticipate. This argument is wrong as a matter of fact and law. Verdegaal's own expert, Dr. Bahme, admitted that Stoller discussed the problem of high temperature caused by the exothermic reaction, and that the heel could function as a heat sink. n3 In any event, Union Oil's burden of proof was limited to establishing that Stoller disclosed the same process. It did not have the additional

burden of proving that Stoller recognized the heat sink capabilities of using a heel. Even assuming Stoller did not recognize that the heel of his process functioned as a heat sink, that property was inherently possessed by the heel in his disclosed process, and, thus, his process anticipates the claimed invention. *See In re Oelrich, 666 F.2d 578, 581, 212 U.S.P.Q. (BNA) 323, 326 (CCPA 1981); In re Swinehart, 58 C.C.P.A. 1027, 439 F.2d 210, 212-13, 169 U.S.P.Q. (BNA) 226, 229 (CCPA 1971).* [**13] The pertinent issues are whether Stoller discloses the process of adding urea and sulfuric acid to a previously-made batch of product, and whether that base would in fact act as a heat sink. On the entirety of the record, these issues could only be resolved in the affirmative.

n3 There is no dispute that the percentage of heel described in Stoller meets the percentage of heat sink required by the claims.

On appeal Verdegaal improperly attempts to attack the status of the Stoller patent as prior art, stating in its brief:

> Verdegaal also introduced evidence at trial that the Stoller patent is not prior art under *35 U.S.C. § § 102*(e)/103. Professor Chisum testified that the Stoller patent, in his opinion, was not prior art. . . . This conclusion finds support in *In re Wertheim, 646 F.2d 527, 209 U.S.P.Q. (BNA) 554 (CCPA 1981),* and 1 *Chisum on Patents § 3.07*[3].

Appellee Brief at 27 (record cite omitted). Seldom have we encountered such blatant distortion [**14] of the record. A question about the status of the Stoller disclosure as prior art did arise at trial. Union Oil asserted that, even though the Stoller patent issued after the *'343* patent, Stoller was prior art under section 102(e) as of its filing date which was well before the filing date of Verdegaal's application. Professor Chisum never testified that the Stoller patent was *not* prior art, but rather, stated that *he did not know* whether it was prior art. An excerpt from the pertinent testimony leaves no doubt on this point:

> Q. (Mr. Sutton): And do you know whether the Stoller patent is prior art to the application of the Verdegaal patent?
> A. (Prof. Chisum): I don't know that it is, no.

We find it even more incredible that Verdegaal would attempt to raise an issue with respect to the status of the Stoller patent given that the case was submitted to the jury with the instruction that the original Stoller patent application was prior art. n4 Verdegaal made no objection to that instruction below, and in its appeal briefs, the instruction is cavalierly ignored.

n4 The jury instruction read:

> Stoller filed two patent applications -- an original application on October 30th, 1978, and a second on February 7th, 1980. Under the patent laws, the claims of the 343 patent are invalid if you find that the original application (Exhibit BL) anticipates the process claimed in the 343 patent.

[**15]

In sum, Verdegaal is precluded from arguing that the Stoller patent should not be considered prior art. *See Fed. R. Civ. P. 51; Weinar v. Rollform Inc., 744 F.2d 797, 808, 223 U.S.P.Q. (BNA) 369, 375 (Fed. Cir. 1984), cert. denied, 470 U.S. 1084, 105 S. Ct. 1844, 85 L. Ed. 2d 143 (1985); Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp., 739 F.2d 604, 615, 222 U.S.P.Q. (BNA) 654, 662* (Fed. Cir.), *cert. denied, 469 U.S. 1038, 83 L. Ed. 2d 405, 105 S. Ct. 516 (1984).* n5

n5 Union Oil also argues that Verdegaal's counsel misled the jury by its closing rebuttal argument:

> But I think it's important to keep in mind that [Stoller] couldn't have been a prior patent because it issued a month after the Verdegaal patent had issued.

We disapprove of Verdegaal's tactic which would form the basis for a grant of a motion for a new trial but for our conclusion that outright reversal of the ruling on the motion for JNOV is in order.

[**16]

[*634] After considering the record taken as a whole, we are convinced that Union Oil established anticipation of claims 1, 2, and 4 by clear and convincing

evidence and that no reasonable juror could find otherwise. Consequently, the jury's verdict on validity is unsupported by substantial evidence and cannot stand. Thus, the district court's denial of Union Oil's motion for JNOV must be reversed.

Conclusion

Because the issues discussed above are dispositive of this case, we do not find it necessary to reach the other issues raised by Union Oil. n6 In accordance with this opinion, we reverse the portion of the judgment entered on the jury verdict upholding claims 1, 2, and 4 of the *'343* patent as valid under section 102(e) and infringed.

n6 It should not be inferred that all of these issues were properly before us. Union Oil appears to assume that on appeal it may dispute the resolution of any *issue* which is denominated an "issue of law" even though it was not raised in its motion for JNOV. This is incorrect. *See Railroad Dynamics, 727 F.2d at 1511, 220 U.S.P.Q. (BNA) at 934.*

[**17]

REVERSED.

LEXSEE 802 F.2D 1376

HYBRITECH INCORPORATED, Appellant, v. MONOCLONAL ANTIBODIES, INC., Appellee

Appeal No. 86-531

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

802 F.2d 1367; 1986 U.S. App. LEXIS 20347; 231 U.S.P.Q. (BNA) 81

September 19, 1986

PRIOR HISTORY: [**1]

Appealed from: U.S. District Court for the Northern District of California. Judge Conti.

DISPOSITION:

Reversed and Remanded.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff appealed a judgment of the United States District Court for the Northern District of California in favor of defendant in plaintiff's infringement action. The district court held that all claims of plaintiff's patent were invalid for anticipation under *35 U.S.C.S. § 102*(g), for obviousness under *35 U.S.C.S. § 103,* and under *35 U.S.C.S. § 112.*

OVERVIEW: Plaintiff, a corporation in the business of developing diagnostic kits, sued defendant corporation, alleging that the manufacture and sale of defendant's diagnostic kits infringed plaintiff's patent with claims defining a variety of sandwich assays using monoclonal antibodies. The district court ruled in favor of defendant, holding that all claims of plaintiff's patent were invalid for anticipation under *35 U.S.C.S. § 102*(g), for obviousness under § 103, and under *35 U.S.C.S. § 112.* The court reversed, holding that although some of plaintiff's inventor's laboratory notebooks were not witnessed until a few months to one year after their writing due to plaintiff's inexperience as a start-up company, the notebooks were still corroborative and clearly showed conception of the claimed invention before others. Furthermore, the large number of references relied upon by the district court to show obviousness skirted around but did not as a whole suggest the claimed invention.

OUTCOME: The court reversed the judgment of the district court holding plaintiff's patent invalid in all respects, since the district court's decision was based on clearly erroneous factual findings, and remanded the matter for determination of plaintiff's claim of infringement.

LexisNexis(R) Headnotes

Civil Procedure > Appeals > Reviewability > Preservation for Review
[HN1] See *Fed. R. Civ. P. 52(a).*

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review
Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN2] Findings of the district court may be reversed only if clearly erroneous. A finding is clearly erroneous when, although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review
Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN3] If documents or objective evidence contradict a witness's story, clear error may be found even in a trial

court's finding purportedly based on a credibility determination.

Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
Patent Law > Infringement Actions > Burdens of Proof
[HN4] Under *35 U.S.C.S. § 282,* a patent is presumed valid, and the one attacking validity has the burden of proving invalidity by clear and convincing evidence. Notwithstanding that the introduction of prior art not before the examiner may facilitate the challenger's meeting the burden of proof on invalidity, the presumption remains intact and on the challenger throughout the litigation, and the clear and convincing standard does not change.

Patent Law > Anticipation & Novelty > Invention
[HN5] *35 U.S.C.S. § 102*(g) states that a person shall be entitled to a patent unless before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. Section 102(g) relates to prior inventorship by another in this country and retains the rules governing the determination of priority of invention.

Patent Law > Date of Invention & Priority > Conception Date
Patent Law > Anticipation & Novelty > General Overview
[HN6] See *35 U.S.C.S. § 102*(g).

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN7] Reduction to practice, and conception as well, is a legal determination subject to review free of the clearly erroneous standard. Findings of fact supporting that legal conclusion are reviewed under the clearly erroneous standard.

Patent Law > Date of Invention & Priority > General Overview
Patent Law > Anticipation & Novelty > General Overview
[HN8] Conception is the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice. Actual reduction to practice requires that the claimed invention work for its intended purpose, and constructive reduction to practice occurs when a patent application on the claimed invention is filed.

Patent Law > Anticipation & Novelty > Fact & Law Issues
[HN9] It is axiomatic that for prior art to anticipate under *35 U.S.C.S. § 102* it has to meet every element of the claimed invention, and that such a determination is one of fact.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN10] An obviousness determination under *35 U.S.C.S. § 103,* whether the claimed invention would have been obvious at the time the invention was made, is reviewed free of the clearly erroneous standard. However, the underlying factual inquiries -- scope and content of the prior art, level of ordinary skill in the art, and differences between the prior art and the claimed invention -- integral parts of the subjective determination involved in § 103, are reviewed under that standard. Objective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered before a conclusion on obviousness is reached.

Patent Law > Claims & Specifications > Enablement Requirement > Proof
Patent Law > Claims & Specifications > Enablement Requirement > Standards & Tests
[HN11] Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention, is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive, and is determined as of the filing date of the patent application. Furthermore, a patent need not teach, and preferably omits, what is well known in the art.

Patent Law > Claims & Specifications > Best Mode > Adequate Disclosure
[HN12] Under *35 U.S.C.S. § 112,* the specification shall set forth the best mode contemplated by the inventor of carrying out his invention. In order to find that the best mode requirement is not satisfied, it must be shown that the applicant knew of and concealed a better mode than he disclosed.

Patent Law > Claims & Specifications > Definiteness > General Overview
Patent Law > Claims & Specifications > Enablement Requirement > General Overview
[HN13] Under the law pertaining to indefiniteness, if the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise

as the subject matter permits, the courts can demand no more.

COUNSEL:

Douglas E. Olson, Lyon & Lyon, of Los Angeles, California, argued for Appellant. With him on brief were James W. Geriak and Bradford J. Duft.

David J. Brezner, Flehr, Hohback, Test, Albritton & Herbert, of San Francisco, California, argued for Appellee. Barry E. Britschneider and Herbert I. Cantor, of Washington, District of Columbia, of Counsel.

JUDGES:

Rich, Davis, and Smith, Circuit Judges.

OPINIONBY:

RICH

OPINION:

[*1368] RICH, Circuit Judge.

This appeal is from the August 28, 1985, decision of the *United States District Court for the Northern District of California, 623 F. Supp. 1344, 227 U.S.P.Q. (BNA) 215,* in favor of defendant Monoclonal Antibodies, Inc. (Monoclonal) holding that all 29 claims of plaintiff's patent No. 4,376,110 entitled "Immunometric Assays Using Monoclonal Antibodies" ('110 patent), issued to Dr. Gary S. David and Howard E. Greene and assigned to Hybritech Incorporated (Hybritech), are invalid as anticipated under *35 USC § 102*(g), for obviousness under § 103, and under § 112 first [**2] and second paragraphs. We reverse and remand.

Background

Vertebrates defend themselves against invasion by microorganisms by producing antibodies, proteins which can complex with the invading microorganisms and target them for destruction or removal. In fact, any foreign molecule of sufficient size can act as a stimulus for antibody production. Such foreign molecules, or antigens, bear particular sites or epitopes that represent antibody recognition sites. B cell lymphocytes, the cells that actually produce antibodies, recognize and respond to an epitope on an antigen by reproducing or cloning themselves and then producing antibodies specific to that epitope. Even if the antigen is highly purified, the lymphocytes will produce antibodies specific to different epitopes on the antigen and so produce antibodies with different specificities. Furthermore, because the body is exposed to many different antigens, the blood of a vertebrate will contain antibodies to many different antigenic substances.

Scientists and clinicians have long employed the ability of antibodies to recognize and complex with antigens as a tool to [*1369] identify or label particular cells or molecules [**3] and to separate them from a mixture. Their source of antibodies has been primarily the serum separated from the blood of a vertebrate immunized or exposed to the antigen. Serum, however, contains a mixture of antibodies directed to numerous antigens and to any number of epitopes on a particular antigen. Because such a mixture of antibodies arises from many different clones of lymphocytes, it is called "polyclonal."

Recent technological advances have made it possible to isolate and cultivate a single clone of lymphocytes to obtain a virtually unlimited supply of antibodies specific to one particular epitope. These antibodies, known as "monoclonal antibodies" because they arise from a single clone of lymphocytes, are produced by a relatively new technology known as the hybridoma. Hybridomas are produced by fusing a particular cancer cell, the myeloma cell, with spleen cells from a mouse that has been injected or immunized with the antigen. These fusions are isolated by transferring them to a growth fluid that kills off the unfused cancer cells, the unfused spleen cells dying off by themselves. The fused hybrid spleen and myeloma cells, called hybridomas, produce antibodies to the [**4] antigen initially injected into the mouse. The growth fluid containing the hybridomas is then diluted and put into individual test tubes or wells so that there is only one hybridoma per tube or well. Each hybridoma then reproduces itself and these identical hybridomas each produce identical monoclonal antibodies having the same affinity and specificity. In this way, a virtually unlimited supply of identical antibodies is created, directed to only one epitope on an antigen rather than, as with polyclonal antibodies, to many different epitopes on many different antigens.

In addition to the specificity of antibodies to particular epitopes discussed above, antibodies also have a characteristic "sensitivity," the ability to detect and react to antigens. Sensitivity is expressed in terms of "affinity:" the greater an antibody's ability to bind with a particular antigen, the greater the antibody's affinity. The strength of that antibody-antigen bond is in part dependent upon the antibody's "affinity constant," expressed in liters per mole, for the antigen.

Immunoassays, the subject matter of the '110 patent, are diagnostic methods for determining the presence or amount of antigen in [**5] body fluids such as blood or urine by employing the ability of an antibody to recognize and bind to an antigen. Generally, the extent to

which the antibody binds to the antigen to be quantitated is an indication of the amount of antigen present in the fluid. Labelling the antibody or, in some cases, the antigen, with either a radioactive substance, I125, or an enzyme makes possible the detection of the antibody-antigen complex. In an extreme case, where the fluid sample contains a very low level of the antigen, binding might not occur unless the antibodies selected or "screened" for the procedure are highly sensitive.

In the case of a "competitive" immunoassay, a labelled antigen reagent is bound to a limited and known quantity of antibody reagent. After that reaction reaches equilibrium, the antigen to be detected is added to the mixture and competes with the labelled antigen for the limited number of antibody binding sites. The amount of labelled antigen reagent displaced, if any, in this second reaction indicates the quantity of the antigen to be detected present in the fluid sample. All of the antigen attached to the antibody will be labelled antigen if there is no antigen [**6] in the test fluid sample. The advantage of this method is that only a small amount of antibody is needed, its drawback, generally, that the system must reach equilibrium, and thus produces results slowly.

In the case of a "sandwich" assay, otherwise known as an immunometric assay, the latter being a term coined by Dr. Lawton Miles in 1971, a quantity of unlabelled antibody reagent is bound to a solid support surface such as the inside wall of a test tube containing a complex of the fluid sample [*1370] containing the antigen to be detected and a labelled *antibody* reagent. The result is an insoluble three part complex referred to as a sandwich having antibody bread and antigen filling. This figure is illustrative of the sandwich concept:

[SEE ILLUSTRATION IN ORIGINAL]

The advantage of the sandwich assay is that it is fast and simple, its drawback that enormous quantities of antibodies are needed.

Hybritech

Hybritech, started in 1978 and joined thereafter by coinventors Green and Dr. David, has, since 1979, been in the business of developing diagnostic kits employing monoclonal antibodies that detect numerous antigens and thus a broad range of conditions [**7] such as pregnancy, cancer, growth hormone deficiency, or hepatitis. Examples of antigens include influenza viruses, immunoglobulin E (IgE) which indicates allergic reaction, human chorionic gonadotropin (HCG) which indicates pregnancy, and prostatic acid phosphatase (PAP) which indicates prostate cancer, to name a few. Dr. Adams, a business-experienced scientist, joined the company in May 1980 as head of research and development. The '110 patent, application for which was filed August 4, 1980, issued March 8, 1983, with claims defining a variety of sandwich assays using monoclonal antibodies. Claim 19, apparently the broadest of the twenty-nine in the patent, is directed generally to a sandwich assay and reads (emphasis ours):

> 19. *In an immunometric assay* to determine the presence or concentration of an antigenic substance in a sample of a fluid comprising forming a ternary complex of a first labelled antibody, said antigenic substance, and a second antibody said second antibody being bound to a solid carrier insoluble in said fluid wherein the presence of the antigenic substance in the samples is determined by measuring either the amount of labelled antibody bound to [**8] the solid carrier or the amount of unreacted labelled antibody, *the improvement comprising* employing monoclonal antibodies having an affinity for the antigenic substance of at least about 10<8> liters/mole for each of said labelled antibody and said antibody bound to a sold carrier.

Claim 1, directed particularly to a reverse sandwich assay, explained infra, reads:

> 1. A process for the determination of the presence of [sic, or] concentration of an antigenic substance in a fluid comprising the steps:
>
> > (a) contacting a sample of the fluid with a measured amount of a soluble first monoclonal antibody to the antigenic substance in order to form a soluble complex of the antibody and antigenic substance present in said sample, said first monoclonal antibody being labelled;
> > (b) contacting the soluble complex with a second monoclonal antibody to the antigenic substance, said second monoclonal antibody being bound to a solid carrier, said solid carrier being [*1371]

insoluble in said fluid, in order to form an insoluble complex of said first monoclonal antibody, said antigenic substance and said second monoclonal antibody bound to said solid carrier;
(c) [**9] separating said solid carrier from the fluid sample and unreacted labelled antibody;
(d) measuring either the amount of labelled antibody associated with the solid carrier or the amount of unreacted labelled antibody; and
(e) relating the amount of labelled antibody measured with the amount of labelled antibody measured for a control sample prepared in accordance with steps (a)-(d), said control sample being known to be free of said antigenic substance, to determine the presence of antigenic substance in said fluid sample, or relating the amount of labelled antibody measured with the amount of labelled antibody measured for samples containing known amounts of antigenic substance prepared in accordance with steps (a)-(d) to determine the concentration of antigenic substance in said fluid sample, the first and second monoclonal antibodies having an affinity for the antigenic substance of at least about 10 <8> liters/mole.

The District Court Decision

Hybritech sued Monoclonal March 2, 1984, for damages and an injunction alleging that the manufacture and sale of Monoclonal's diagnostic kits infringed the '110 patent. Trial without a jury began on August 5, 1985, and [**10] concluded August 23, 1985, thirty witnesses having been heard and over 2,000 pages of transcript generated. The district court produced the reported opinion, findings, and conclusions, which use nearly verbatim Monoclonal's *pre-trial* brief and *pre-trial proposed* findings of fact and conclusions of law, in three days, in support of the judgement now on appeal.

The district court held that the claimed subject matter of the '110 patent was neither conceived nor actually reduced to practice before May 1980, and was anticipated under § 102(g) by the actual reduction to practice of the invention by Drs. Uotila and Ruoslahti at the La Jolla Cancer Research Foundation (LJCRF) as early as November of 1979 and by the actual reduction to practice of the invention by Drs. Oi and Herzenberg (Oi/Herzenberg work) at the Stanford University Laboratory as early as July 1978, later published in December of 1979.

The district court also held the claims of the '110 patent invalid for obviousness from the Oi/Herzenberg work in view of (1) a February 1979 article by M. E. Frankel and W. Gerhard (Frankel article) which discloses high-affinity monoclonal antibodies, and apparently in view of [**11] numerous other references including; (2) the work of Nobel Prize winners G. Kohler and C. Milstein disclosing a Nobel Prize-worthy method for producing monoclonal antibodies in vitro (outside the body) published in an August 7, 1975, article; (3) U.S. Patent No. *4,244,940* issued to Jeong et al. disclosing a simultaneous polyclonal assay (Jeong), U.S. Patent No. *4,098,876* to Piasio et al. disclosing a reverse polyclonal sandwich assay (Piasio), U.S. Patent No. *4,016,143* to Schurrs et al. disclosing a forward polyclonal sandwich assay (Schurrs); (4) a July 1979 publication by A. C. Cuello et al. disclosing the use of monoclonal antibodies in competitive assays; and (5) eight articles dated between January 1979 and March 6, 1980, "predicting" that monoclonal antibodies would be used in future immunoassays. n1

n1 With respect to obviousness, one portion of the district court's opinion apparently relies on all of the above listed references, (1) -- (5), for the obviousness holding while a later portion entitled "CONCLUSIONS OF LAW" relies on only the Oi/Herzenberg and Frankel articles. Furthermore, the district court did not state that the LJCRF work was considered for purposes of § 103, although we recognize that § 102(g) prior art can be used for § 103.

[**12]

The district court also invalidated the patent on various grounds based on *35 USC § 112,* first and second paragraphs, as hereinafter discussed.

[*1372] A. *The References*

1. *Kohler and Milstein's Nobel Prize-Winning Work: Producing Monoclonal Antibodies In Vitro For the First Time*

In early immunoassay work, polyclonal antibodies produced in vivo (in the body) in mice were used to bind with the antigen to be detected in the body fluid sample. Mice were immunized by injection with antigen so that the lymphocytes in their bodies produced antibodies that attacked the injected antigen. Those polyclonal antibodies were withdrawn from the animal's blood and used in immunoassays. The major problem was that when the mice's immune systems changed or the mice died, the antibodies changed or died too; supply was limited and uncertain.

As the examiner was aware, Kohler and Milstein developed a technique not only for producing antibodies in vitro, independent of a living body, thus eliminating dependence on a particular animal, but for in vitro production of monoclonal antibodies by hybridomas, discussed in the Background section, supra.

Given that [**13] sandwich assays require enormous amounts of antibodies, companies like appellant and appellee, which utilize monoclonal antibodies for sandwich assays, would not be in business were it not for the work of Kohler and Milstein.

2. *The Work of Drs. Ruoslahti, Uotila, and Engvall at the La Jolla Cancer Research Foundation (LJCRF) in 1979 and 1980*

Dr. Ruoslahti performed mostly competitive immunoassays using polyclonal antibodies to alphafetoprotein (AFP) antigens at the City of Hope since 1970. Dr. Uotila joined him in late 1978 to perform immunoassays using monoclonal antibodies to AFP. After producing monoclonal antibodies to AFP and performing competitive radio immunoassays (RIA -- a competitive assay that uses a radioactive label) with monoclonal antibodies at the City of Hope in mid-1979, Drs. Ruoslahti, Uotila and Engvall left LJCRF.

In the fall of 1979, September or October according to Dr. Uotila, discussion and work began on using monoclonal antibodies to AFP in a sandwich assay. Dr. Uotila, the principal researcher in this particular endeavor, generated six notebooks while at the City of Hope and LJCRF. The next-to-last page of notebook four contained a note to [**14] Dr. Uotila from Dr. Ruoslahti reading:

> Sometime you should enzyme label a good monoclonal antibody so that you can set up a sandwich assay. If you use two monoclonal antibodies, you may be able to do the assay with a single incubation, since the monoclonal antibodies are likely to be directed against different determinants and not compete with one another.

Although Dr. Uotila's notebook pages were, for the most part, unsigned, undated, and uncorroborated, Dr. Ruoslahti's testimony, placed the date of this note at about October 1979 by referring to the first pages of notebook five which were dated in early November 1979. Dr. Ruoslahti testified that one curve on one graph on page 43D of notebook five showed a successful simultaneous sandwich assay using monoclonal antibodies about November 5, 1979, although no data supporting that graph could be found elsewhere in the notebook. He further testified that the affinity of the monoclonal antibodies used for that test was not calculated until 1980 but that the raw data necessary for that calculation was generated in 1979.

Dr. Uotila stated in her deposition (she did not testify at trial) that she started work on a sandwich [**15] assay using monoclonal antibodies between October 4 and the end of that month, 1979, and that she could not remember the procedure used nor was there enough information in her notebook, including page 43D, to refresh her memory. She did remember, although she continued work on this assay because the tests did not yield repeatedly good curves without which she would not publish her work, that the assay on page 43D was successful. Dr. Engvall testified about a discussion of Dr. Uotila's monoclonal antibody work with [*1373] her while at the City of Hope and about first performing a sandwich assay after arriving at LJCRF in 1979.

3. *The Work of Drs. Oi and Herzenberg at the Stanford University Laboratory in 1978 Published in December 1979*

Drs. Oi and Herzenberg used monoclonal antibodies to "map" epitopes or determine the number and location of different antibody binding sites on a known quantity of IgE antigen by attaching to it an antibody bound to a carrier and exposing that antigen to other monoclonal antibodies. The antibodies either attached to epitopes on the antigen or were blocked from doing so by the other monoclonal antibodies, depending on the location and [**16] number of epitopes; if the epitopes on the antigen were too close together and the number of antibodies too great, few antibodies would bind to the antigen.

Hybritech points out that both Dr. Herzenberg and Dr. Oi testified that *their work did not involve determining the presence or quantity of antigen*, that they had no idea what the affinities of the monoclonal antibodies used were, and that those values were never calculated.

One unsigned, unwitnessed page from three large laboratory notebooks, which Hybritech argues is insufficient because it does not identify the chemical reagents or protocol used, was relied on by Monoclonal to establish actual reduction to practice of the Oi/Herzenberg work in 1978 to establish a case of § 102(g) prior invention by another. The district court agreed with Monoclonal that the Oi/Herzenberg work anticipated the claimed invention and, in addition, combined this work with the Frankel publication to hold that the claimed subject matter was obvious under § 103.

4. *The Frankel Article: Monoclonal Antibodies Having Affinities of 10 (9) liters/mole*

Frankel describes an RIA (radioimmunoassay) method for the rapid determination of affinity [**17] constants for monoclonal antibodies produced from hybridomas. The article states that the assay used is applicable only to antibodies with binding constants of about 10 <10> liters/mole and discloses the binding constants for antibodies to several closely related strains of influenza virus.

The district court found that Frankel disclosed monoclonal antibodies having the affinity constants claimed in the '110 patent, 10 <8> to over 10 <9> liters/mole.

5. *The Cuello Article and the Jeong, Piasio, and Schurr Patents Considered by the Examiner*

Cuello, dated July 1979, states that it describes the usefulness of monoclonal antibodies in the characterization and localization of neurotransmitters such as Substance P, a peptide clearly associated with the transmission of primary sensory information in the spinal cord. The article discloses producing monoclonal antibodies from hybrid myelomas (hybridomas), their use in conventional radioimmunoassay techniques, and the benefits from doing so which flow from the ability to derive permanent cell lines capable of continuous production of highly specific antibodies.

The district court found that the examiner twice rejected all of the [**18] claims of the '110 patent based on Cuello alone or in combination with the Jeong, Piasio, and Schurr references which disclose various sandwich assays using polyclonal antibodies. The court also found that the examiner allowed the claims after they were amended to include the 10 <8> affinity limitation and after Richard Bartholomew, a Hybritech employee, submitted an affidavit alleging the advantages of using monoclonal rather than polyclonal antibodies in sandwich assays.

Apparently based on the testimony of Monoclonal's expert witness Judith Blakemore, a named inventor of the Jeong patent, manager of antibody programs at Bio-Rad Laboratories from 1975 to 1982, and currently manager of monoclonal antibody therapeutics at Cetus Corporation, a Hybritech competitor in immunoassay diagnostics, the district court stated that the "reasons for allowance were not well-founded because (1) the alleged advantages were [*1374] expected as naturally flowing from the well-known natural characteristics of monoclonal antibodies . . .; (2) . . . were not significant . . .; or (3) were at best minor," although they were "argued to the examiner as if they were" important. These were Monoclonal's [**19] words from its pretrial submission adopted by the court.

6. *The References That "Predicted" the Use of Monoclonal Antibodies in Immunoassays*

The district court stated, again in Monoclonal's words, that "it is of the utmost importance" that the advantages of monoclonal antibodies were "predicted by a number of authorities," eight to be exact, not important enough to list here, after the Kohler and Milstein discovery and after monoclonal antibodies became available.

B. *The Claimed Subject Matter of the '110 Patent*

Hybritech argues that the district court's determination that there is no credible evidence of conception or reduction to practice of the '110 invention before May 1980 is error because Dr. David's laboratory notebooks, Nos. 21 and 24, clearly show successful sandwich assays using monoclonal antibodies in August, September, and October of 1979. At the least, argues Hybritech, the invention was conceived in January of 1979, long before Drs. Ruoslahti, Engvall, and Uotila began work on a sandwich assay using monoclonal antibodies, and diligence was thereafter exercised until constructive reduction to practice occurred by the filing of the '110 patent application [**20] on August 4, 1980.

Dr. David and Greene testified that pages 2118 to 2122 of Dr. David's notebook, dated January 4, 1979, and witnessed January 30, 1979, disclose the generic conception of the invention in the context of the physical support structure used to carry out a sandwich assay, and Dr. David testified on redirect that (1) Page 1128 of notebook 21, dated May 27, 1979, recorded an early attempt at a sandwich assay that failed, (2) on August 3, 1979, as recorded at page 1166, a sandwich assay using monoclonal antibody 068 attached to a solid carrier, a radio-labelled 068 antibody, and a hepatitis antigen from an Abbott Labs polyclonal competitive assay kit was successfully performed, and (3) a sandwich assay using a

bound 259 antibody, a radio-labelled 068 antibody, and a hepatitis antigen was successfully performed on September 21, 1979. Hybritech also urges that work in October 1979 directed to determining whether certain monoclonal antibodies were recognizing the same or different determinants, was a reduction to practice.

Monoclonal points out that these notebook pages do not expressly state that monoclonal antibodies of 10 <8> liters/mole affinity were used in a sandwich [**21] assay and that the May, August, and September notebook entries were not witnessed until about the time Dr. Adams, experienced in patent matters, joined Hybritech and advised its researchers on properly recording laboratory work. They therefore claim that actual reduction to practice was not shown before May 1980.

OPINION

I. *Review Under Rule 52(a) Fed. R. Civ. P.*

Rule 52(a) [HN1] "ensures care in the preparation of an opinion . . . and provides appellate courts with the benefit of the District Court's insights into a case," *Pentec, Inc. v. Graphic Controls Corp., 776 F.2d 309, 318, 227 U.S.P.Q. (BNA) 766, 772 (Fed. Cir. 1985)* (Harvey, Senior District Judge, concurring) by requiring a district court to "find the facts specially and state separately its conclusions of law thereon." With the exception of the first eight paragraphs, the first half of the district court's opinion here is Monoclonal's *pretrial* brief and the last three pages of the opinion are Monoclonal's *pretrial* findings of fact and conclusions of law. The district court adopted the above documents [**22] virtually verbatim, with the exception of portions of each concerning inequitable conduct and noninfringement, apparently without inviting a response from Hybritech, resulting in a repetitious (as the district court admitted in [*1375] the opinion), sometimes internally inconsistent, and hard to follow opinion that presents us with a difficult task in gleaning the basis for many of the conclusions. For some of the findings, submitted before trial, no supporting evidence was introduced at trial.

The Supreme Court, in *Anderson v. City of Bessemer City, N.C., 470 U.S. 564, 105 S. Ct. 1504, 84 L. Ed. 2d 518 (1985),* strongly criticized the practice of "verbatim adoption of findings of fact prepared by prevailing parties, particularly when those findings have taken the form of conclusory statements unsupported by citation to the record." *Anderson*, supra at 1511. This court also has cautioned against the adoption of findings, especially when proposed by a party before trial, as here, and stated that the likelihood of clear error in those findings increases in such a situation. *Lindemann Maschinenfabrik v. American Hoist and Derrick, 730 F.2d 1452, 221 U.S.P.Q. (BNA) 481, 485 (Fed. Cir. 1984).* [**23] Notwithstanding our misgivings about whether the findings in this case, prepared before any evidence was introduced, satisfy the objectives of Rule 52(a) -- a carefully prepared opinion providing the reviewing court with the benefit of the district court's *reasoned insights* into the case -- those [HN2] findings are the district court's and may be reversed only if clearly erroneous. *See Anderson*, supra, at 1511; *Lindemann, 730 F.2d at 1457, 221 U.S.P.Q. at 485.*

"A finding is clearly erroneous when, although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co., 333 U.S. 364, 395, 92 L. Ed. 746, 68 S. Ct. 525 (1948).* "This standard plainly does not entitle a reviewing court to reverse the finding of the trier of fact simply because it is convinced that it would have decided the case differently." *Anderson*, supra, at 1511. In other words, "if the district court's account of the evidence is plausible in light [**24] of the record viewed in its entirety" or "where there are two permissible views of the evidence," the factfinder cannot be clearly erroneous. *Anderson*, supra, at 1511 (quoting *United States v. Yellow Cab Co., 338 U.S. 338, 70 S. Ct. 177, 94 L. Ed. 150 (1949)).* This is so, stated the Court in dictum, *see Anderson*, supra, at 1516 (Blackmun, J., concurring), even when the district court's findings rest on physical or documentary evidence or inferences from other facts and not on credibility determinations. *See also Rule 52(a) Fed. R. Civ. P.* (as amended Aug. 1, 1985). If the latter are involved, "Rule 52 demands even greater deference to the trial court's findings" but a trial judge may not "insulate his findings from review by denominating them credibility determinations"; [HN3] if documents or objective evidence contradict the witness's story, clear error may be found even in a finding purportedly based on a credibility determination. *Anderson*, supra, at 1512-13. We proceed in light of all these principles.

II. *Presumption of Validity*

[**25] [HN4] Under *35 USC § 282,* a patent is presumed valid, and the one attacking validity has the burden of proving invalidity by clear and convincing evidence. *See, e.g., American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360, 220 U.S.P.Q. (BNA) 763, 770 (Fed.Cir. 1984).* Notwithstanding that the introduction of prior art not before the examiner may facilitate the challenger's meeting the burden of proof on invalidity, the presumption remains intact and on the challenger throughout the litigation, and the clear and convincing standard does not change. *See, e.g., Jervis B. Webb Co. v. Southern Systems, Inc., 742 F.2d 1388, 1392 & n.4, 222 U.S.P.Q. (BNA) 943, 945 & n.4 (Fed. Cir. 1984).* The only indication that the district court

recognized the presumption of validity and its proper application was its statement that "the key issue in this case is whether the defendant has overcome the presumption of nonobviousness." That statement, however, speaks only part of the truth; the presumption of validity goes to validity of the patent in relation to the patent statute *as a* [**26] *whole*, not just to nonobviousness under section 103.

[*1376] III. *Prior Invention of Another, 35 USC § 102(g)*

Section 102(g) [HN5] states that a person shall be entitled to a patent unless "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it." Section 102(g) "relates to prior inventorship by another in this country" and "retains the rules governing the determination of priority of invention. . . ." *Kimberly-Clark Corp. v. Johnson & Johnson, 745 F.2d 1437, 1444, 223 U.S.P.Q. (BNA) 603, 606 (Fed. Cir. 1984)* (quoting P.J. Federico, *Commentary on the New Patent Act, 35 USCA page 1*, at 19 (1954)). Section 102(g) says: [HN6] "In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."

[**27] [HN7] Reduction to practice, and conception as well, is a legal determination subject to review free of the clearly erroneous standard. *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd., 731 F.2d 831, 837, 221 U.S.P.Q. (BNA) 561, 565-66 (Fed. Cir. 1984); D.L. Auld Co. v. Chroma Graphics Corp., 714 F.2d 1144, 1151, 219 U.S.P.Q. (BNA) 13, 18 (Fed. Cir. 1983).* Findings of fact supporting that legal conclusion are, of course, reviewed under the clearly erroneous standard.

[HN8] Conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." 1 *Robinson On Patents* 532 (1890); *Coleman v. Dines, 754 F.2d 353, 359, 224 U.S.P.Q. (BNA) 857, 862 (Fed. Cir. 1985).* Actual reduction to practice requires that the claimed invention work for its intended purpose, *see, e.g., Great Northern Corp. v. Davis Core & Pad Co., 782 F.2d 159, 165, 228 U.S.P.Q. (BNA) 356, 358,* (Fed. [**28] Cir. 1986), and, as has long been the law, constructive reduction to practice occurs when a patent application on the claimed invention is filed. *Weil v. Fritz, 572 F.2d 856, 865 n.16, 196 U.S.P.Q. (BNA) 600, 608 n.16 (CCPA 1978)* (citing with approval *Automatic Weighing Machine Co. v. Pneumatic Scale Corp., 166 F. 288 (1st Cir. 1909)).*

After a review of the record in its entirety, including the numerous corroborating Hybritech laboratory notebooks, internal documents, and pertinent testimony, we hold clearly erroneous the district court's finding that there is no clear or corroborated evidence "with regard to when before May 1980, the idea of actually using monoclonals in sandwich assays" was conceived or, more properly, or when the *claimed invention* was conceived, and therefore reverse the court's holding, as a matter of law, that Hybritech's inventors did not conceive the claimed invention before May 1980.

Hybritech's claim of conception, generally, is evidenced by the sometimes sparsely documented work of a start-up company whose first small advances evolved into the myriad activities of a mature company with efforts directed toward developing [**29] the claimed invention by first employing the Kohler and Milstein technology to produce the necessary monoclonal antibodies and using those antibodies in diagnostic sandwich assay kits. There is no doubt that exploiting monoclonal antibodies for use in sandwich assays was one of the major objectives of Hybritech. In a letter to Pharmacia Fine Chemicals dated April 26, 1979, Greene, in responding to Pharmacia's interest in Hybritech's products, outlined the latter's "efforts to bring the exciting new hybridoma technology into routine medical use" and its exploration of "several intriguing concepts for which monoclonals may open up new immunodiagnostic techniques heretofore infeasible with animal serums." Although company minutes in early 1979 contain little about the claimed subject matter and some of the discussions thereon, such as Greene's and Dr. Adams' conversation about monoclonal sandwich assays when the former was trying to woo Dr. Adams to join Hybritech were unrecorded, the Hybritech laboratory notebooks and the [*1377] nature of Hybritech's research program fully corroborate the testimonial evidence of conception and thus clearly support our holding that Hybritech conceived [**30] the claimed invention before LJCRF.

Dr. David's January 1979 notebook describes, in detail, as explained by Greene and Dr. David at trial, a nylon apparatus that undoubtedly could be used for performing a sandwich assay using monoclonal antibodies, although Dr. David testified on cross-examination that at that time Hybritech had not yet developed any monoclonal antibodies, including attaching one of the reagents to a solid carrier ring, contacting that ring with a fluid sample in a microtiter plate well, adding a labelled reagent to the well after rinsing, and then "counting" or measuring the amount of either the labelled or unlabelled reagent after a

prescribed time and second rinsing. The notebook then describes the procedure for detecting an antibody "(a-x)" to an antigen "(x)" complete with diagrams and text, both illuminated by Dr. David at trial. The notebook further states, "Alternatively, if one wished to quantitate an antigen, y, the identical procedure would be followed, except that reagents would be reversed, i.e. the reaction would be:" and there follows a clear illustration of an antibody attached to a solid carrier reacting with an antigen to form a complex, and that [**31] complex reacting with a second labelled antibody. The notebook was signed by Dr. David on January 4, 1979, and witnessed and signed on January 30 of the same year by Dr. Curry, the first cell biologist hired at Hybritech to set up the hybridoma production program.

Dr. David testified on direct that monoclonal antibodies were developed in the following months: antigens were purchased from outside sources and purified before being injected into mice; the spleen cells from those mice were fused with myelomas; and the resultant hybridomas were separated into well plates for development, and a radioimmunoassay procedure was carried out to determine the affinity of the antibodies.

The May 1979 failed sandwich assay, witnessed in May 1980, corroborates Dr. David's testimony that a polyclonal antibody bound to be a solid carrier and a labelled monoclonal antibody were used in a sandwich assay with an antigen from Abbott Labs' Ausria polyclonal diagnostic kit for hepatitis. No binding was detected.

Dr. David testified about the experiment documented in the August 1979 notebook, a sandwich assay with a hepatitis antigen from an Abbott Labs Ausria kit with two Hybritech 068 monoclonal [**32] antibodies, one attached to a solid carrier bead and the other labelled; the purpose of the experiment was to quantitate the antigen. The notebook corroborates Dr. David's testimony that the test was positive and lists the counts per minute of the labelled antibody. Defendant Monoclonal's expert Ciotti testified about this experiment:

> Also, of course, it is limited to -- it is limited to hepatitis antigen. And without a generic conception, it would just be merely a -- if it did work for its intended purpose -- which I would assume for purposes of discussion -- *it would be a reduction to practice of one embodiment.* And without a corresponding generic conception, I don't think it would be held to be the making of the invention in terms of, for instance, in claim 19. [Emphasis ours.]

Dr. David further testified that the September 21, 1979, record in David's notebook, witnessed months later, shows a reverse sandwich assay using a bound 259 monoclonal antibody and a labelled 068 monoclonal antibody with a hepatitis antigen with results confirmed by a dose response curve. n2 Hybritech further alleges that a laboratory notebook page dated October 1979 is a reduction [**33] to practice of the [*1378] claimed invention but fails to cite any related testimony or other evidence in support thereof.

> n2 A dose response curve is antigen concentration plotted against the signal produced by labelled antibody in an immunoassay. The signal increases with increasing antigen concentration in a successful assay but at some point decreases when the antigen concentration becomes too high.

Finally, the record shows that the claimed affinity limitation "of at least about 10 <8> liters/mole" was determined and appreciated during the course of the development of the claimed subject matter. Dr. David and Dr. Adams separately testified that the screening procedures used by Hybritech ensured that only monoclonal antibodies having at least 10 <8> liters/mole affinity would be used in assays. An October 1979 internal memorandum from Greene to the staff states, "To improve comparisons we will express all affinities to the base ten to the eighth which represents the lower end of the usable range." [**34]

We are left with the definite and firm conviction that a mistake has been committed because the district court's account of the evidence that "there was no credible evidence of conception before May 1980" is insupportable. There is such evidence. The laboratory notebooks, alone, are enough to show clear error in the findings that underlie the holding that the invention was not conceived before May 1980. That some of the notebooks were not witnessed until a few months to one year after their writing does not make them incredible or necessarily of little corroborative value. Admittedly, Hybritech was a young, growing company in 1979 that failed to have witnesses sign the inventors' notebooks contemporaneously with their writing. Under a reasoned analysis and evaluation of all pertinent evidence, however, we cannot ignore that Hybritech, within a reasonable time thereafter, prudently had researchers other than those who performed the particular experiments witness the notebooks in response to Tom Adams' advice. The notebooks clearly show facts underlying and contemporaneous with conception of the

claimed invention and in conjunction with the testimony of Dr. David and Greene, [**35] and others, are altogether legally adequate documentary evidence, under the law pertaining to conception, of the formation in the minds of the inventors of a definite and permanent idea of the complete and operative invention as it was thereafter applied in practice. We thus are not moved by Monoclonal's argument that the findings of fact underlying conception are based on credibility determinations and are more sacrosanct than usual. *See Anderson*, supra, at 1512-13.

1. *LJCRF Is Not Prior Art*

Hybritech laboratory notebooks and the uncontradicted testimony of Dr. David and Mr. Greene show that development of the claimed invention proceeded diligently through the rest of 1979 and 1980, there being absolutely no evidence of record nor even argument by Monoclonal that Hybritech was not diligent in its efforts to reduce to practice the claimed invention during the period January 1979 to the '110 application filing date of August 4, 1980. We therefore hold as a matter of law that Hybritech's conception, which was before LJCRF conceived the claimed invention, coupled by diligence to its constructive reduction to practice by the filing of the '110 application, entitle Hybritech [**36] to priority over LJCRF. *See 35 USC § 102*(g). The work of LJCRF is therefore not prior art.

We also note that there is inadequate factual basis for the district court's holding that LJCRF reduced the claimed invention to practice as early as November 1979 because the only evidence that corroborates the testimony of Ruoslahti, Uotila, and Engvall is the note from Ruoslahti to Uotila, see section A, 2, supra, which indisputably is not the claimed invention, and the *one* curve from *one* graph from only one page, 43D, of the six Uotila notebooks. After a reasoned examination, analysis, and evaluation of this pertinent evidence we conclude that it falls far short of showing the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice," *see Coleman, 754 F.2d at 359, 224 U.S.P.Q. at 862,* and therefore is legally inadequate to support even a holding of *conception* of [*1379] the claimed invention by LJCRF personnel in 1979.

(1) It is undisputed that page 43D was not signed, witnessed, or dated; (2) the deposition testimony of [**37] Uotila was that she could not remember the procedure used to arrive at the dose-response curve on page 43D and there was not enough information in her notebook to refresh her memory; (3) the testimony of Ruoslahti was that he could find *no* data in the notebook supporting that graph, none of the *later* graphs shown there represented successful assays and that "especially after this was done, we ran into more severe problems. And it took us a while to do away with the problems;" (4) Ruoslahti also testified that they never determined, in 1979, the affinities of the monoclonal antibodies they used, and that the title of page 43D had been altered at some point -- the word "inhibition" had been crossed out and "sandwich" written in; and (5) the testimony of Engvall was that there was nothing about the shape of those curves which indicates that they were sandwich assays. We also note, as evidence bearing upon the credibility of Ruoslahti's testimony (that LJCRF actually reduced the claimed invention to practice in 1979), that when LJCRF attempted to provoke an interference in the PTO with Hybritech based on the U.S. filing of an application that was the counterpart to a Swedish application [**38] disclosing similar subject matter, LJCRF could not demonstrate even a *prima facie* reduction to practice prior to Hybritech's August 4, 1980, filing date. During that proceeding, the earliest dates Ruoslahti set down on paper to support conception and reduction to practice were in 1980.

2. *The Work of Oi/Herzenberg Is Not the Claimed Invention*

[HN9] It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention, and that such a determination is one of fact. *See, e.g., Lindemann, supra, 730 F.2d at 1458, 221 U.S.P.Q. at 485; Great Northern Corp. v. Davis Core & Pad Co., 782 F.2d 159, 165, 228 U.S.P.Q. (BNA) 356, 358 (Fed. Cir. 1986).* Section 102(g) upon which the district court relied is one type of "anticipation," i.e., prior invention by another of the same invention. Drs. Oi and Herzenberg testified that their work did not involve detecting the presence of or quantitating antigen but a determination of the number and location of epitopes on a *known* quantity of antigen. Although this work did [**39] involve a sandwich assay to the extent that an antigen was sandwiched between two monoclonal antibodies, it is clear that the similarity between that work and the claimed invention goes no further. Furthermore, both doctors testified that they did not know the affinities of the antibodies that were used in their mapping work and in fact never calculated them. Ciotti, Monoclonal's expert, testified that the 10<8> affinity limitation cannot be found anywhere in the Oi/Herzenberg work. Again we are left with a definite and firm conviction that a mistake was made because that work does not meet every element of the claimed invention. The district court's finding to the contrary is clearly erroneous.

We note that the district court, in also holding the patent invalid under § 103, next considered, combined the Oi/Herzenberg work with the Frankel reference, one

justifiable inference therefrom being that the court recognized that Frankel discloses a claim *element* that Oi/Herzenberg does not, namely, at least about 10<8> liters/mole affinity.

IV. *Obviousness, 35 USC § 103*

[**40] [HN10] A section 103 obviousness determination -- whether the claimed invention *would have been* (not "would be" as the court repeatedly stated because Monoclonal's pretrial papers used that improper language) obvious at the time the invention was made is reviewed free of the clearly erroneous standard although the underlying factual inquiries -- scope and content of the prior art, level of ordinary skill in the art, n3 and differences between the prior art [*1380] and the claimed invention -- integral parts of the subjective determination involved in § 103, are reviewed under that standard. Objective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered *before* a conclusion on obviousness is reached and is not merely "icing on the cake," as the district court stated at trial. *See Lindemann, supra, 730 F.2d at 1461, 221 U.S.P.Q. at 488; Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 218 U.S.P.Q. (BNA) 871 (Fed. Cir. 1983); Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 219 U.S.P.Q. (BNA) 857 (Fed. Cir. 1983); W.L. Gore & Associates v. Garlock, Inc., 721 F.2d 1540, 220 U.S.P.Q. (BNA) 303, 314 (Fed. Cir. 1983).* [**41]

n3 Although the district court failed expressly to find the level of ordinary skill in the art at the time the invention was made, it did make reference to "people working in immunology aware of the Kohler and Milstein discovery" which we deem an accurate finding for the purposes of that portion of the *Graham* factual inquiries.

1. *The Eight Articles "Predicting" Widespread Use of Monoclonal Antibodies*

Before discussing the more pertinent references in this case -- the Oi/Herzenberg and Frankel works -- we cull the other prior art references relied on by the trial court.

First, the latest four of the eight articles that the court stated were of the "utmost importance" because they "predicted" that the breakthrough in production of monoclonal antibodies by Kohler and Milstein would lead to widespread use of monoclonal antibodies in immunoassays are neither 102(a)/103 nor 102(b)/103 prior art because they are dated between late 1979 and March 6, 1980, well after the date of conception and within one [**42] year of the filing date of the '110 patent.

The earliest four of the eight articles, on the other hand, although clearly prior art, discuss *production* of monoclonal antibodies -- admittedly old after Kohler and Milstein showed how to produce them -- but none discloses sandwich assays. At *most*, these articles are invitations to try monoclonal antibodies in immunoassays but do not suggest how that end might be accomplished. To the extent the district court relied upon these references to establish that it would have been *obvious to try* monoclonal antibodies of 10<8> liters/mole affinity in a sandwich immunoassay that detects the presence of or quantitates antigen, the court was in error. *See Jones v. Hardy, 727 F.2d 1524, 1530, 220 U.S.P.Q. (BNA) 1021, 1026 (Fed.Cir. 1984)* ("Obvious to try" is improper consideration in adjudicating obviousness issue). n4

n4 Finding 10, which states that the invention was contemporaneously developed and disclosed in at least five publications and patent applications not listed above *and dated well after the filing date of the '110 patent but before its issuance* is irrelevant for purposes of the hypothesis based on the three factual inquiries required by § 103 as interpreted by *Graham v. John Deere, 383 U.S. 1, 148 U.S.P.Q. (BNA) 459, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966)* because obviousness must be determined as of the time the invention was made. Additionally, they are of little probative value in this case because they are dated December 1981 at the earliest, more than a year after the August 4, 1980, filing date here and roughly two years after conception occurred. Furthermore, simultaneous development may or may not be indicative of obviousness, the latter being the case here for the above reasons and because the other evidence of nonobviousness is adequate, such occurrences having been provided for in *35 USC § 135. Lindemann, supra, 730 F.2d at 1460-61, 221 U.S.P.Q. at 487; Environmental Designs, Ltd. v. Union Oil Co. of California, 713 F.2d 693, 698 n.7, 218 U.S.P.Q. (BNA) 865, 869 n.7 (Fed. Cir. 1983).*

[**43]

2. *The Kohler and Milstein Work, the Cuello Article and the Jeong, Piasio, and Schurr Patents Considered by the Examiner*

The district court's finding that Kohler and Milstein developed a method for producing monoclonal

antibodies in vitro is correct, but that finding proves no more; although it made possible all later work in that it paved the way for a supply of monoclonal antibodies, it indisputably does not suggest using monoclonal antibodies in a sandwich assay in accordance with the invention claimed in the '110 patent.

The Cuello reference discloses monoclonal antibodies but not in a sandwich assay. The competitive assay in Cuello, moreover, [*1381] uses only one monoclonal antibody and thus in no way suggests the claimed invention wherein a ternary complex of two monoclonal antibodies and an antigen form a sandwich. Furthermore, the court did not explain how this art, by itself or in combination with any of the other art, suggests the claimed subject matter and thus why that combination would have been obvious. We are of the opinion that it does not.

The district court correctly found that the use of polyclonal antibodies in sandwich assays was well known. [**44] The Jeong patent discloses the use of polyclonal antibodies in a simultaneous sandwich assay, with no suggestion that monoclonal antibodies be so used. It is prior art by virtue of § 102(e), application for the patent having been filed September 5, 1978, its effective date as a reference. The Piasio patent, disclosing a reverse sandwich assay using polyclonal antibodies, and Schurrs, disclosing a forward sandwich assay using the same, both § 102(a) prior art, are likewise devoid of any suggestion that monoclonal antibodies can be used in a similar fashion.

3. *The Oi/Herzenberg Work and the Frankel Article*

Clearly, the most pertinent items of prior art not cited by the examiner are the Oi/Herzenberg work, as described in section A, 3, supra, and the Frankel article. As stated in the discussion of Prior Invention of Another (section III, 2, supra), the Oi/Herzenberg work involved mapping epitopes on a known quantity of antigen. It was not concerned with and does not disclose using monoclonal antibodies of at least 10<8> liters/mole affinity. Oi and Herzenberg testified that they did not know the affinity of the antibodies used, and Ciotti testified that nowhere in that [**45] work is there mention of monoclonal antibody affinity of at least 10<8> liters/mole. On this basis, we conclude that the Oi/Herzenberg work is qualitatively different than the claimed invention; the former is directed to mapping epitopes on a known quantity of antigen and the latter to determine the "presence or concentration of an antigenic substance in a sample of fluid . . . ." We disagree with Monoclonal that these are "essentially the same thing." Furthermore, it is perfectly clear that this work in no way suggests using monoclonal antibodies of the affinity claimed in the '110 patent. It is because of these differences between the Oi/Herzenberg work and the claimed invention that the fact that an antigen was sandwiched between two monoclonal antibodies in the course of Oi's and Herzenberg's work is not sufficient basis to conclude that the claimed invention would have been obvious at the time it was made to a person of ordinary skill in the art.

Likewise, a conclusion that the invention would have been obvious cannot properly be reached when the Oi/Herzenberg work is considered in view of the Frankel article. Frankel teaches a method for rapid determination of affinity constants [**46] for monoclonal antibodies, some of which clearly have affinities of the order defined by the claims, but does not in any way suggest using two of those antibodies in a sandwich to assay an antigen by forming a ternary complex of labelled antibody, the antigenic substance, and a bound antibody wherein the presence of the antigenic substance is determined by measuring either the amount of labelled antibody bound to a solid carrier or the amount of unreacted labelled antibody. The mere existence of prior art disclosing how to measure the affinity of high affinity monoclonal antibodies is insufficient to support a holding of obviousness. Hybritech's claims define a *process* that *employs* monoclonal antibodies, and does not merely claim antibodies of high affinity. In view of the fact that the Oi/Herzenberg work is not directed to an assay as claimed and does not disclose antibodies of at least 10<8> liters/mole affinity, and further that Frankel fails to suggest using such antibodies in a sandwich assay, the Frankel article does not compensate for the substantial difference between the Oi/Herzenberg work and the claimed subject matter, and therefore those references in combination [**47] cannot support a holding of obviousness.

[*1382] 4. *Objective Evidence of Nonobviousness*

In one part of its opinion the court found that "the commercial success of the kits *may* well be attributed to the business expertise and acumen of the plaintiff's personnel, together with its capital base and marketing abilities" (emphasis ours) and later that "where commercial success is based on the sudden availability of starting materials, in this instance the availability of monoclonal antibodies as a result of the Kohler and Milstein discovery, business acumen, marketing ability, and capital sources, no causal relationship is proven." (Citation omitted.)

i. *Commercial Success: Hybritech's Diagnostic Kits Grabbed a Substantial Market Share*

The undisputed evidence is that Hybritech's diagnostic kits had a substantial market impact. The first diagnostic kit sales occurring in mid-1981, sales increased seven million dollars in just over one year,

from $6.9 million in 1983 to an estimated $14.5 million in 1984; sales in 1980 were nonexistent. Competing with products from industry giants such as Abbott Labs, Hoffman LaRoche, Becton-Dickinson, and Baxter-Travenol, Hybritech's [**48] HCG kit became the market leader with roughly twenty-five percent of the market at the expense of market shares of the other companies. Its PAP kit ranks second only to a product sold by Dupont's New England Nuclear, surpassing products from Baxter-Travenol, Abbott, and others. Hybritech's other kits, indisputably embodying the invention claimed in the '110 patent, obtained similar substantial market positions.

Although the district court did not provide its insights into why commercial success was due to business acumen and not to the merits of the claimed invention, Monoclonal urges in support that it was due to Hybritech's spending disproportionate sums on marketing, 25-30% of income. The undisputed evidence was that expenditures of *mature* companies in this field are between 17 and 32%. Furthermore, the record shows that advertising makes those in the industry -- hospitals, doctors, and clinical laboratories -- aware of the diagnostic kits but does not make these potential users buy them; the products have to work, and there is no evidence that that is not the case here or that the success was not due to the merits of the claimed sandwich assays -- clearly contrary to [**49] the district court's finding.

The trial court's finding that the "sudden availability of monoclonals" was the reason for the commercial success of Hybritech's diagnostic kits (Finding 11) is unsupported by the record and clearly erroneous. Monoclonal admits that monoclonal antibodies were available in the United States in *1978*, and the evidence clearly reflects that. Thus, at least *three years* passed between the time monoclonal antibodies were available in adequate supply and the time Hybritech began selling its kits. Especially in the fast-moving biotechnology field, as the evidence shows, that is anything but sudden availability.

ii. *Unexpected Advantages*

Hybritech points to the testimony of three witnesses skilled in the diagnostic field who state that, based on tests done in their laboratories as a result of real-world comparisons in the normal course of research, the diagnostic kits that embody the '110 invention unexpectedly solved long-standing problems. Dr. Hussa, the head of a large referral laboratory and a world-wide consultant, testified that until Hybritech introduced its kits, he and others were very skeptical and had almost exclusively used competitive [**50] assays with a radioactive tracer (RIAs). n5 In relation to an [*1383] HCG Hybritech kit, he testified that he had first thought that the Hybritech HCG kit would not give accurate results for low antigen concentrations because that condition is indicated in the Hybritech kit by a low radioactivity reading, a reading difficult to differentiate from control samples containing no antigen. He also stated that in the past, RIA kits falsely detected HCG in nonpregnant women, a condition which would indicate cancer and surgery. He stated that when he employed the Hybritech HCG kit in such instances it demonstrated, correctly and absent any difficulty interpreting the data, that no HCG was present.

n5 Monoclonal's expert Blakemore testified that of 425 assays on the market in 1979 less than 1% were sandwich assays. Today, sandwich assays constitute the majority of all assays sold.

The record also shows that Blakemore, who testified extensively for Monoclonal that the claimed invention would have been obvious, never used monoclonal antibodies in sandwich assays at Cetus before 1980. Additionally, she did not even mention them in the Jeong patent, of which she was a coinventor, which issued January 13, 1981, long after the beginning of Hybritech's work in this area in 1979.

[**51]

Dr. Blethen, an M.D. holding a Ph.D. in biochemistry, testified that she did not think that the Hybritech HGH kit, for detecting growth hormone in children, would offer any advantage, but she determined that it detected HGH deficiencies in children where conventional RIAs failed to do so. She also stated that the kit does not give false positive readings as do conventional RIA kits, an opinion shared by Dr. Hussa. A third witness, Dr. Herschman, who holds a master's degree in chemistry, testified that he spent years working on the development of an assay that would determine the presence of TSH (thyroid stimulating hormone) with greater sensitivity. He succeeded but discovered that the Hybritech TSH kit had the same sensitivity, the test being performed in four hours rather than the three days his kit required.

Having considered the evidence of nonobviousness required by § 103 and *Graham, supra,* we hold, as a matter of law, that the claimed subject matter of the '110 patent would not have been obvious to one of ordinary skill in the art at the time the invention was made and therefore reverse the court's judgment to the contrary. The large number of references, [**52] as a whole, relied upon by the district court to show obviousness, about twenty in number, skirt all around but do not as a whole suggest the claimed invention, which they must, to

overcome the presumed validity, *Lindemann, 730 F.2d at 1462, 221 U.S.P.Q. at 488, as a whole. See 35 USC § 103; Jones v. Hardy, 727 F.2d 1524, 1529, 220 U.S.P.Q. (BNA) 1021, 1024 (Fed. Cir. 1984).* Focusing on the obviousness of substitutions and differences instead of on the invention as a whole, as the district court did in frequently describing the claimed invention as the mere substitution of monoclonal for polyclonal antibodies in a sandwich assay, was a legally improper way to simplify the difficult determination of obviousness. *See generally Hodosh v. Block Drug Co., 786 F.2d 1136, 229 U.S.P.Q. (BNA) 182 (Fed. Cir. 1986).* n6

> n6 It bears repeating that it is crucial that counsel set forth the law accurately. More particularly, it is the duty of counsel to impart to the judge that the obviousness question properly is whether the *claimed* invention *as a whole would have been* obvious to one of *ordinary* skill in the art *at the time the invention was made*, and that the district court must *expressly* make the three factual determinations required by *Graham* and consider objective evidence of obviousness *before* the legal conclusion of obviousness vel non is made. Submitting to the court language like "any differences . . . would have been obvious," as was done here, violates the axiom that the question is not whether the differences would have been obvious but the claimed invention *as a whole*. Furthermore, arguing that "it would be obvious" rather than that it would *have been* obvious shifts the court's focus to the wrong period of time, namely to a time long after the wrong period of time, namely to a time long after the invention was made, in which, more likely than not, the prior art and the level of ordinary skill in the art are more advanced. *See 35 USC § 103.*

[**53]

With respect to the objective indicia of nonobviousness, while there is evidence that marketing and financing played a role in the success of Hybritech's kits, as they do with any product, it is clear to us on the entire record that the commercial success here was due to the merits of the claimed invention. It cannot be argued on this record that Hybritech's success would have been as great and as prolonged as admittedly it has been if that success were not due to the merits of the invention. The evidence is that these kits compete successfully with numerous others for the trust of persons who have to make fast, accurate, and safe diagnoses. This is not the kind of [*1384] merchandise that can be sold by advertising hyperbole.

V. *Enablement, Best Mode, and Definiteness Under § 112*

The section 112 defense appears to have been an afterthought of both Monoclonal, who briefly but unsuccessfully attempts to defend this utterly baseless determination, and of the district court which adopted the defense from Monoclonal's pretrial papers apparently without knowledge of the applicable law, to highlight, as it stated at trial, that it was part of its job to see that "whoever [**54] wins wins all the way or whoever loses loses all the way." Taken as a whole, the court's comments on § 112 -- split into two parts, one from Monoclonal's pretrial brief and the other from the adopted pretrial findings and conclusions -- are internally inconsistent. The opinion states that the patent fails to disclose how (1) to make monoclonal antibodies; (2) to screen for proper monoclonal antibodies; and (3) to measure monoclonal antibody affinity and therefore the specification is nonenabling and does not satisfy the best mode requirement, and the claims are indefinite. We discuss each of these in turn.

1. *Enablement*

[HN11] Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention, *Raytheon Co. v. Roper Corp., 724 F.2d 951, 960, 220 U.S.P.Q. (BNA) 592, 599 (Fed. Cir. 1983),* is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive, *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., 750 F.2d 1569, 1576, 224 U.S.P.Q. (BNA) 409, 413 (Fed. Cir. 1984),* [**55] and is determined as of the filing date of the patent application, which was August 4, 1980. *See W. L. Gore and Associates v. Garlock, Inc., 721 F.2d 1540, 1556, 220 U.S.P.Q. (BNA) 303, 315 (Fed. Cir. 1983).* Furthermore, a patent need not teach, and preferably omits, what is well known in the art. *Lindemann, 730 F.2d at 1463, 221 U.S.P.Q. at 489.*

The record fully supports the '110 patent's statement that

> The monoclonal antibodies used for the present invention are obtained by the [hybridoma] process discussed by Milstein and Kohler. . . . The details of this process are well known and not repeated here.

The district court itself stated that the "method for producing monoclonal antibodies in vitro was well known prior to the alleged invention of the '110 patent," and used the "sudden availability of monoclonal

antibodies" produced by the Kohler and Milstein discovery to support, albeit erroneously, its finding of a lack of nexus between the merits of the claimed invention and its commercial success. The court then about-faced and held the '110 patent deficient because it fails to teach how to make monoclonal antibodies. [**56]

With respect to screening, the only permissible view of the evidence is that screening methods used to identify the necessary characteristics, including affinity, of the monoclonal antibodies used in the invention were known in the art and that the '110 patent contemplated one of those. At trial, Monoclonal's counsel stated "it is a procedure that was known in '78." In similar fashion, the district court held that the claimed subject matter would have been obvious in part because the "existence of monoclonal antibodies *having the affinity constants claimed in the patent was well known* prior to the alleged invention. . . ." [Emphasis ours.] Furthermore, there was not a shred of evidence that undue experimentation was required by those skilled in the art to practice the invention. We hold as a matter of law that the '110 patent disclosure is enabling.

2. *Best Mode*

[HN12] "The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention." *35 USC § 112.* Because not complying with the best mode requirement amounts [**57] to concealing the preferred mode contemplated by the applicant at the time of filing, in order to find that the best mode requirement is not satisfied, it must be shown that [*1385] the applicant knew of and concealed a better mode than he disclosed. *DeGeorge v. Bernier, 768 F.2d 1318, 1324, 226 U.S.P.Q. (BNA) 758, 763 (Fed. Cir. 1985)* (quoting with approval *In re Sherwood, 613 F.2d 809, 204 U.S.P.Q. (BNA) 537 (CCPA 1980)).* The only evidence even colorably relating to concealment is testimony by various Hybritech employees that sophisticated, competent people perform the screening and that the screening process is labor-intensive and time-consuming. It is not plausible that this evidence amounts to proof of concealment of a best mode for screening or producing monoclonal antibodies for use in the claimed '110 process, and therefore we are of the firm conviction that the district court's finding that the best mode requirement was not satisfied is clearly erroneous.

3. *Indefiniteness*

The basis of the district court's holding that the claims are indefinite is that "they do not disclose how infringement may be avoided because antibody [**58] affinity cannot be estimated with any consistency." (Conclusion 6.) Even if the district court's finding in support of this holding -- that "there is no standard set of experimental conditions which are used to estimate affinities" -- is accurate, [HN13] under the law pertaining to indefiniteness -- "if the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more," *Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 U.S.P.Q. (BNA) 634, 641 (Fed. Cir. 1985)* -- the claims clearly are definite. The evidence of record indisputably shows that calculating affinity was known in the art at the time of filing, and notwithstanding the fact that those calculations are not precise, or "standard," the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits. As a matter of law, no court can demand more.

VI. [**59] *Motions*

Monoclonal's motion to strike Appendices A and B of Hybritech's reply brief as being beyond the page limit applicable to reply briefs is granted as to Appendix A but denied as to Appendix B, the latter having been helpful in culling the often non-supportive citations to the record by Monoclonal.

Hybritech's motion to supplement the record with a Monoclonal advertisement not considered at trial is denied. Any adverse impact that the disposition of these two motions has upon either party is more than outweighed by this court's patience with the seemingly endless flow of post-argument argumentative papers.

VII. *Conclusion*

The judgment of the district court holding the patent in suit invalid is *reversed* in all respects, and the case is *remanded* for a determination of the issue of infringement which the court held was moot.

REVERSED AND REMANDED.

LEXSEE 766 F.2D 531

IN RE JOHN A. DONOHUE

No. 85-868

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

766 F.2d 531; 1985 U.S. App. LEXIS 15739; 226 U.S.P.Q. (BNA) 619

July 3, 1985

PRIOR HISTORY: [**1]

Appealed from: U.S. Patent & Trademark Office Board of Appeals.

DISPOSITION:

Affirmed.

CASE SUMMARY:

PROCEDURAL POSTURE: Appellant challenged a decision of the United States Patent and Trademark Office Board of Appeals sustaining the rejection of the claims in his patent application.

OVERVIEW: The United States Patent and Trademark Office Board of Appeals (Board) rejected appellant's patent application for his claimed inventions of acid compounds used to produce polymers to form shaped objects, finding that a previous patent had anticipated them. The Board found it irrelevant that the prior patent holder had not synthesized the particular compounds in question. On appeal, the court reviewed the record and concluded that the Board had properly considered an affidavit that had not been part of the record in prior proceedings because the affidavit created a new issue. Moreover, the court held that it did not matter that the invention had not been made previously, as a method of preparing it was obvious to one of ordinary skill in the art. Rejection due to anticipation was proper because the limitation of the claim could be found in a single reference.

OUTCOME: The court affirmed the Board's judgment, concluding that it did not matter that the prior patent holder had not synthesized appellant's compounds, as the limitation could be found in a prior reference and, therefore, was anticipated.

LexisNexis(R) Headnotes

Patent Law > Anticipation & Novelty > General Overview
Patent Law > Claims & Specifications > Enablement Requirement > General Overview
[HN1] Prior art under *35 U.S.C.S. § 102* (b) must sufficiently describe the claimed invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling. It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.

Patent Law > Claims & Specifications > Enablement Requirement > General Overview
Patent Law > Nonobviousness > Elements & Tests > General Overview
[HN2] Whether or not the claimed invention has been made previously is not essential to a determination that a method of preparing it would have been known by, or would have been obvious to, one of ordinary skill in the art.

Patent Law > Claims & Specifications > Claim Language > General Overview

Patent Law > Anticipation & Novelty > General Overview

[HN3] An anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device.

COUNSEL:

William Magidson, of Chicago, Illinois, argued, for Appellant.

Harris A. Pitlick, Associate Solicitor, U.S. Patent & Trademark Office, of Arlington, Virginia, argued for Appellee. With him on the brief were Joseph F. Nakamura, Solicitor and John W. Dewhirst, Associate Solicitor.

JUDGES:

Markey, Chief Judge, Baldwin, Circuit Judge, and Miller, * Senior Circuit Judge.

* Judge Miller assumed senior status effective June 6, 1985.

OPINIONBY:

MILLER

OPINION:

[*531] Miller, Senior Circuit Judge.

This is an appeal from the decision of the U.S. Patent and Trademark Office ("PTO") Board of Appeals ("board") sustaining the [*532] final rejection of appellant's claims n1 1, 2, 5, 6, 7, 25, and 28. We affirm.

n1 In application Serial No. 263,900, filed May 15, 1981, for Tetramethylbiphenylcarboxylic Acids and Derivatives Thereof, which is a division of Serial No. 60,909, filed July 26, 1979, and a continuation of Serial No. 622,649, filed October 15, 1975, which is a continuation-in-part of Serial No. 517,506, filed October 24, 1974.

[**2]

BACKGROUND

The subject matter of this appeal was previously before this court's predecessor in *In re Donohue, 632 F.2d 123, 207 U.S.P.Q. (BNA) 196 (CCPA 1980)* (*Donohue I*"). n2 There is no need to discuss the details of that opinion; however, a summary of the pertinent facts is appropriate for a full understanding of the issues before us.

n2 *Donohue I* involved application No. 622,649. *See* note 1, *supra*.

The present invention relates to 2,2',6,6'-tetramethylbiphenyl-4,4'-dicarboxylic acid compounds which are suitable for producing polymers used to form shaped objects, such as film, fibers, or molded parts. Claim 1, which is the sole independent claim on appeal, is illustrative:

> 2,2',6,6'-tetramethylbiphenyl-4,4'-dicarboxylic acid compound comprising said acid, an acyl halide derivative thereof, or a simple ester thereof.

The PTO has rejected all the appealed claims under *35 U.S.C. § 102*(b) "as anticipated by Nomura [et al.], optionally in view of Lincoln and Walker [**3] [et al.]."

Nomura et al. ("Nomura") n3 discloses twelve 2,2',6,6'-tetramethylbiphenyls ("TMBP") which are 4,4'-disubstituted with NH[2], NMe[2], OH, OMe, Cl, Br, I, CO[2]H, CO[2]Me, CN, NO[2], or H substituents. Methods of preparing all these compounds, except those disubstituted with CO[2]H or CO[2]Me, are set forth in Nomura. Nomura's disclosure of how to make 4,4'-dinitrile (or dicyano) TMBP is particularly significant, because Lincoln n4 and Wagner et al. ("Wagner") n5 teach, generally, the preparation of carboxylic acids from nitriles by hydrolysis.

n3 Yujiro Nomura and Yoshito Takeuchi, "Substituent Effects in Aromatic Proton Nuclear Magnetic Resonance Spectra. Part VI. [<2>H[6]] Benzene-induced Solvent Shifts in 4,4'-Disubstituted 2,2',6,6'-Tetramethylbiphenyls and Related Compounds," *J. Chem. Soc'y (B)*, 956-60 (1970).

n4 U.S. Patent No. *3,876,691*, issued April 8, 1975, on application No. 351,696, filed April 16, 1973, for a "Process for the Hydrolysis of Nitriles."

n5 Wagner et al., *Synthetic Organic Chemistry* 412-15 (John Wiley & Sons, N.Y., N.Y.) (1965).

[**4]

In *Donohue I*, a majority of the Court of Customs and Patent Appeals ("CCPA") affirmed the PTO's rejection of appealed claims 1, 5, 6, and 7 n6 under *35 U.S.C. § 102*(b). *Id. at 127, 207 U.S.P.Q. at 200.* The basis for the rejection was, as it is here, Nomura with reference to Lincoln and Wagner. *Id. at 126, 207 U.S.P.Q. at 199.*

n6 Claim 1 in *Donohue I* differs from claim 1 of the present appeal only in that the latter includes the limitation "comprising said acid, an acyl halide derivative thereof, or a simple ester thereof." Claims 5, 6, and 7 of *Donohue I* specify the same dependent features as in the presently-appealed claims of the same number.

A minority of the CCPA voted to reverse the PTO's decision, because they concluded it was uncertain from the text of Nomura that the dicarboxylic acid TMBP and dimethyl ester TMBP were ever prepared. *Id. at 129, 207 U.S.P.Q. at 201.* Accordingly, Nomura's disclosure was, in the minority's view, no more than a mere naming of the claimed compounds [**5] which is insufficient to constitute an enabling disclosure. *Id. at 129, 207 U.S.P.Q. at 201.*

After *Donohue I*, the presently-appealed application was filed. During prosecution before the PTO, appellant submitted an affidavit under *37 C.F.R. § 1.132* executed by Dr. Ellis K. Fields ("Fields affidavit"). In this affidavit, Dr. Fields states that he wrote to Dr. Yoshito Takeuchi, one of the authors of Nomura, to ask whether the disclosed dicarboxylic acid TMBP or dimethyl ester TMBP compounds were ever synthesized, as indicated in Nomura. Dr. Takeuchi responded by stating that these compounds were not synthesized, and Dr. [*533] Fields submitted his affidavit to that effect.

Despite the Fields affidavit, the examiner finally rejected the claims, and an appeal to the board was filed. The board affirmed the rejection of the claims on the grounds stated *supra*, holding that it was bound by *Donohue I.* As to the Fields affidavit, the board held that whether the authors of Nomura actually prepared the claimed compounds is not "material or relevant"; rather, the key factor in evaluating the adequacy of a reference's disclosure was deemed to be whether that disclosure [**6] would have been enabling, and the board determined that the CCPA had decided that question with respect to Nomura.

ANALYSIS

Appellant has made a record different from that in *Donohue I* by submitting the Fields affidavit. This new record presents a new issue of patentability with respect to whether the previously-sustained anticipation rejection can still be maintained. In view of this new issue, the PTO properly declined to make a formal *res judicata* rejection and addressed the question of whether the Fields affidavit overcomes the rejection of the claims based on Nomura. *See In re Ackermann, 58 C.C.P.A. 1405, 444 F.2d 1172, 1176, 170 U.S.P.Q. (BNA) 340, 343 (1971); In re Russell, 58 C.C.P.A. 1081, 439 F.2d 1228, 1230, 169 U.S.P.Q. (BNA) 426, 428 (1971); In re Herr, 54 C.C.P.A. 1315, 377 F.2d 610, 611, 153 U.S.P.Q. (BNA) 548, 549 (1967).*

Appellant argues that the Fields affidavit, which states that the authors of Nomura did not make the disclosed dicarboxylic acid TMBP and dimethyl ester TMBP compounds, overcomes the PTO's rejection. It is urged that *Donohue I* and *In re Samour, 571 F.2d 559, 197 U.S.P.Q. (BNA) 1 (CCPA 1978),* require, *inter alia* [**7] , that a *35 U.S.C. § 102*(b) rejection based on a primary reference disclosing a claimed compound in conjunction with one or more references which teach how to make that compound, should be sustained only if the claimed compound was actually made. We disagree.

It is well settled that [HN1] prior art under *35 U.S.C. § 102* (b) must sufficiently describe the claimed invention to have placed the public in possession of it. n7 *In re Sasse, 629 F.2d 675, 681, 207 U.S.P.Q. (BNA) 107, 111 (CCPA 1980); In re Samour, 571 F.2d at 562, 197 U.S.P.Q. at 4; see also Reading & Bates Construction Co. v. Baker Energy Resources Corp., 748 F.2d 645, 651-52, 223 U.S.P.Q. (BNA) 1168, 1173 (Fed. Cir.1984).* Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. *See In re LeGrice, 301 F.2d at 939, 133 U.S.P.Q. at 373-74.* Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling. *In re Borst, 52 C.C.P.A. 1398, 345 F.2d 851, 855, 145 U.S.P.Q. (BNA) 554, 557 (1965), cert.* [**8] *denied, 382 U.S. 973, 83 S. Ct. 537, 15 L. Ed. 2d 465 (1966).* It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.

n7 This rule is based on the "described in a printed publication" language in *35 U.S.C. § 102*(b). *See In re LeGrice, 49 C.C.P.A. 1124, 301 F.2d 929, 936, 133 U.S.P.Q. (BNA) 365, 371 (1962).*

In re Wiggins, 488 F.2d 538, 179 U.S.P.Q. (BNA) 421 (CCPA 1973) and *In re Sheppard, 52 C.C.P.A. 859, 339 F.2d 238, 144 U.S.P.Q. (BNA) 42 (1964),* do not

support a contrary view. In those cases, the references were deemed insufficient, because they stated that attempts to prepare the claimed compounds were unsuccessful. Such failures by those skilled in the art (having possession of the information disclosed by the publication) are strong evidence that the disclosure of the publication was nonenabling. By contrast, the fact that the author of a publication did not attempt to make his disclosed [**9] invention does not indicate one way or the other whether the publication would have been enabling.

Although *In re Samour* and *Donohue I* mention that the claimed invention in each case was apparently produced in conjunction with the anticipatory reference, this is a far cry from proclaiming that such production [*534] is required to meet the enablement requirement. *In re Samour*, in fact, states:

> [HN2] Whether or not [the claimed invention] has been made previously is not essential to a determination that a method of preparing it would have been known by, or would have been obvious to, one of ordinary skill in the art.

571 F.2d at 563 n.6, 197 U.S.P.Q. at 4 n.6. Therefore, the statements in *In re Samour* and *Donohue I* that the claimed invention was made previously serve to point out the absence of any strong evidence of nonenablement as in *Wiggins* and *Sheppard. See In re Donohue, 632 F.2d at 126 n.6, 207 U.S.P.Q. at 199 n.6.*

At oral argument, appellant also challenged the correctness of the CCPA's holding in *In re Samour* and *Donohue I* that several references can be used together to support an anticipation rejection. However, [**10] we are bound by the CCPA's decision in those cases. *South Corp. v. United States, 690 F.2d 1368, 1370-71, 215 U.S.P.Q. (BNA) 657, 658 (Fed. Cir. 1982)* (in banc). At the same time, we have no difficulty with the rejections made in *In re Samour* and *Donohue I.*

It is elementary that [HN3] an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device. *E.g., Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771, 218 U.S.P.Q. (BNA) 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026, 104 S. Ct. 1284, 79 L. Ed. 2d 687, 224 U.S.P.Q. (BNA) 520 (1984).* The anticipation rejection used here, as in *In re Samour* and *Donohue I*, is not inconsistent with this rule. *See In re Marshall, 578 F.2d 301, 304, 198 U.S.P.Q. (BNA) 344, 346 (CCPA 1978).* The additional references utilized in this case (viz., Lincoln and Wagner) are not relied upon for suggestion or motivation to combine teachings to meet the claim limitations, as in rejections under *35 U.S.C. § 103. In re Samour, 571 F.2d at 563, 197 U.S.P.Q. at 4-5.* Such reliance would be pointless, because Nomura alone discloses every element claimed. [**11] The purpose of citing Lincoln and Wagner is, instead, to show that the claimed subject matter, as disclosed in Nomura, was in the public's possession. *Id.* Therefore, the anticipation rejection based on Nomura, Lincoln, and Wagner is proper. n8

> n8 *Compare Studiengesellschaft Kohle, M.B.H. v. Dart Industries, Inc., 726 F.2d 724, 220 U.S.P.Q. (BNA) 841 (Fed. Cir. 1984)* (recognized exception occasionally permitting use of additional references in anticipation rejections but holding exception did not apply).

Appellant also argues that the references fail to teach the solubility characteristics and melting point range set forth in dependent claims 25 and 28, respectively. n9 However, where, as here, the dicarboxylic acid TMBP and dimethyl ester TMBP of Nomura are identical to the claimed invention, the properties of Nomura's compounds are inherently the same as those of the claimed invention in the absence of proof to the contrary. *See In re Best, 562 F.2d 1252, 1255, 195 U.S.P.Q. (BNA) 430, 433-34* [**12] *(CCPA 1977).*

> n9 Claims 25 and 28 read as follows:
>
> 25. The acid of Claim 2, said acid being soluble in ether and N-methyl-2-pyrrolidone.
>
> 28. The dimethyl ester of Claim 7, having a melting point of 128-129 degrees C.

In view of the foregoing, the board's decision is affirmed.

AFFIRMED

LEXSEE 116 F.3D 1454

JERRY GECHTER, ROBERT L. POKRESS, JEFFREY A. FRIED, and G. WAYNE ANDREWS, Appellants, v. WAYNE A. DAVIDSON and DIANA S. WINTER, Cross-Appellants.

96-1374, 96-1375, (Interference No. 103,051)

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

116 F.3d 1454; 1997 U.S. App. LEXIS 14073; 43 U.S.P.Q.2D (BNA) 1030

June 12, 1997, Decided

SUBSEQUENT HISTORY: [**1] As Amended June 13, 1997.

PRIOR HISTORY: Appealed from: U.S. Patent and Trademark Office Board of Patent Appeals and Interferences.

DISPOSITION: VACATED AND REMANDED.

CASE SUMMARY:

PROCEDURAL POSTURE: Parties appealed a judgment of the United States Patent and Trademark Office Board of Patent Appeals and Interferences, which held both parties' patent claims anticipated by a prior patent.

OVERVIEW: In his patent application, one of the cross-appellants copied the patent claims made by one appellant in his pending patent application. The United States Patent and Trademark Office Board of Patent Appeals and Interferences found patent applications of both appellants and cross-appellants invalid, as they were anticipated by a prior patent. Appellants argued that the Board erroneously interpreted the disputed patent claim in its anticipation finding. The court vacated the Board's decision, holding that the Board had not set forth specific findings of fact or conclusions of law that would allow the court to adequately review whether a prior patent had anticipated both parties' patent applications.

OUTCOME: The decision of the United States Patent and Trademark Office Board of Patent Appeals and Interferences was vacated because it did not adequately set forth specific findings of fact or conclusions of law supporting its decision.

LexisNexis(R) Headnotes

Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > Patentability & Priority Determinations
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > Claims & Specifications > Claim Language > Dependent Claims
[HN1] The United States Court of Appeals for the Federal Circuit has jurisdiction over appeals of final decisions on patents made by the United States Patent and Trademark Office Board of Patent Appeals and Interferences, pursuant to *35 U.S.C.S. § 141* (1994) and *28 U.S.C.S. § 1295*(a)(4)(A) (1994).

Patent Law > Anticipation & Novelty > Elements
[HN2] Under *35 U.S.C.S. § 102,* every limitation of a patent claim must identically appear in a single prior art reference for it to anticipate the claim.

Patent Law > Anticipation & Novelty > Elements
Patent Law > Anticipation & Novelty > Fact & Law Issues
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
[HN3] When the United States Patent and Trademark Office Board of Patent Appeals and Interferences (Board) delivers a finding of anticipation that presents a question of fact, the United States Court of Appeals for the Federal Circuit's review is limited to deciding

whether such finding was clearly erroneous. Implicit in a review of the Board's patent anticipation analysis is that the claim must first have been correctly construed to define the scope and meaning of each contested limitation. However, claim construction is a question of law and therefore reviewed de novo.

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
[HN4] See *35 U.S.C.S. § 141.*

Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > U.S. Patent & Trademark Office Proceedings > General Overview
Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN5] For an appellate court to fulfill its role of judicial review, it must have a clear understanding of the grounds for the decision being reviewed. When the opinion explaining the decision lacks adequate fact-findings, meaningful review is not possible, frustrating the very purpose of appellate review as well as this court's compliance with its statutory mandate. Therefore, the mandate to review under *35 U.S.C.S. § 141* implies inherent power in the United States Court of Appeals for the Federal Circuit to require that the United States Patent and Trademark Office Board of Patent Appeals and Interferences' decision be capable of review.

Patent Law > Anticipation & Novelty > Elements
Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > General Overview
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
[HN6] Necessary findings must be expressed with sufficient particularity to enable the United States Court of Appeals for the Federal Circuit, without resort to speculation, to understand the reasoning of the United States Patent and Trademark Office Board of Patent Appeals and Interferences and to determine whether it applied the law correctly and whether the evidence supports the underlying and ultimate fact findings. If either the crucial findings on underlying factual issues or the ultimate finding of anticipation is clearly erroneous, the decision must be reversed. Similarly, if the claims were misconstrued, a finding of anticipation must be reversed unless the error was harmless.

Patent Law > Anticipation & Novelty > Elements
Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN7] Like a district court opinion, an opinion of the United States Patent and Trademark Office Board of Patent Appeals and Interferences must contain sufficient findings and reasoning to permit meaningful appellate scrutiny.

Patent Law > Jurisdiction & Review > Standards of Review > Clearly Erroneous Review
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
[HN8] The standard of review of district court fact findings, set forth in *Fed. R. of Civ. P. 52(a)*, is the "clearly erroneous" standard. That is the same standard of review the Court of Appeals for the Federal Circuit applies to fact finding of the United States Patent and Trademark Office Board of Patent Appeals and Interferences in both anticipation and obviousness contexts.

Civil Procedure > Appeals > Standards of Review > Clearly Erroneous Review
Patent Law > Jurisdiction & Review > Standards of Review > Clearly Erroneous Review
[HN9] Because the same clearly erroneous standard of review applies to district court judgments under *Fed. R. Civ. P. 52(a)* and decisions regarding anticipation and obviousness by the United States Patent and Trademark Office Board of Patent Appeals and Interferences, the rule's requirements are instructive, even though not controlling when reviewing a Board judgment under the standard. Under the rule, a district court may not merely state its findings in conclusory terms, but must provide sufficient detail to elucidate the reasoning by which the court reached its ultimate finding on an issue of fact or conclusion on an issue of law. Indeed, as to the facts it must also find subsidiary facts "specially," and not just the ultimate fact, here of anticipation. If it fails to do so, its decision will ordinarily be vacated. The same rule governs when a conclusion on a crucial issue of law is omitted.

Administrative Law > Judicial Review > Standards of Review > Standards Generally
Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN10] Agencies have a duty to provide reviewing courts with a sufficient explanation for their decisions so that those decisions may be judged against the relevant statutory standards, and that failure to provide such an explanation is grounds for striking down the action.

Patent Law > Anticipation & Novelty > Elements
Patent Law > Claims & Specifications > Description Requirement > Means Plus Function

Patent Law > U.S. Patent & Trademark Office Proceedings > Interferences > Patentability & Priority Determinations

[HN11] In reviewing the patentability of an invention, to hold that a prior art reference anticipates a patent claim, the United States Patent and Trademark Office Board of Patent Appeals and Interferences must expressly find that every limitation in the claim was identically shown in the single reference.

Patent Law > Anticipation & Novelty > Fact & Law Issues

Patent Law > U.S. Patent & Trademark Office Proceedings > Examinations > General Overview

Patent Law > Jurisdiction & Review > Standards of Review > General Overview

[HN12] The United States Patent and Trademark Office Board of Patent Appeals and Interferences Board (Board) is required to set forth in its opinions specific findings of fact and conclusions of law adequate to form a basis for review. In particular, the Board's patent anticipation analysis must be conducted on a limitation by limitation basis, with specific fact-findings for each contested limitation and satisfactory explanations for such findings. Patent claim construction must also be explicit, at least as to any construction disputed by parties to the interference or an applicant or patentee in an ex parte proceeding.

COUNSEL: William E. Booth, Fish & Richardson, P.C., of Boston, Massachusetts, argued for appellants. Of counsel were Robert E. Hillman and Mary D. Mosley-Goren, of Boston, Massachusetts, and Barry E. Bretschneider, of Washington, D.C.

Charles L. Warren, Lucent Technologies Inc., of Naperville, Illinois, argued for cross-appellants. With him on the brief was Dennis J. Williamson.

JUDGES: In Banc. Before MICHEL, LOURIE, and SCHALL, Circuit Judges.

OPINIONBY: MICHEL, Circuit Judge.

OPINION: [*1456] MICHEL, Circuit Judge.

On October 26, 1995, the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board) issued a decision in Interference No. 103,051, finding that the independent claims corresponding to the count were unpatentable under *35 U.S.C. § 102* (1994) as anticipated by U.S. Patent No. *4,763,353* (Canale); the dependent claims fell by stipulation. Jerry Gechter, Robert L. Pokress, Jeffrey A. Fried, and G. Wayne Andrews (collectively, Gechter) appeal the unpatentability ruling which invalidates their U.S. Patent No. *5,036,535* (the *'535* patent); [**2] Wayne A. Davidson and Diana S. Winter (collectively, Davidson) cross-appeal the same ruling which effectively rejects the claims in their application, Serial No. 07/748,147. The case was submitted for our decision after oral argument on March 7, 1997. Because the Board failed to set forth findings of fact adequate to enable us to determine whether its decision of anticipation is clearly erroneous, we vacate the Board's decision and remand the case for preparation of an opinion that makes the fact findings and claim construction necessary to make the decision reviewable on appeal.

BACKGROUND

The senior party, Davidson, provoked the interference by copying the claims of Gechter's patent (the *'535* patent) in his application. The claims of both Davidson and Gechter are directed to an automatic call distribution system that automatically distributes calls over a telephone network to a group of telephone operators who may be located distant from the central number and are waiting to receive calls. n1 The *'535* patent has 63 claims, only claims 1 and 49 being independent. Claim 1, which corresponds exactly to the sole count in the interference, recites:

> An automatic call distributing [**3] system for automatically distributing telephone calls placed over a network to one of a plurality of agent stations connected to said network via network service interfaces and providing agent status messages to said network, said system comprising receiving means connected via a network service interface to said network for receiving said agent status messages and call arrival messages from said network indicating that incoming calls have been made on said network, said agent status messages being generated at said agent stations and communicated through said network service interfaces and network to said receiving means, and routing means responsive to said receiving means for generating a routing signal provided to the network to cause said network to establish a connection directly between said incoming call and an agent station through the network so that said connection is external of said routing means.

n1 Because the disposition of this case rests on reviewability, not the merits, we do not describe the technology and discuss the facts only as necessary for this decision.

In its Final Decision, the Board found the independent claims corresponding to the count to [**4] be unpatentable to both Gechter and Davidson as anticipated by Canale. n2 The Board limited its anticipation analysis essentially to two paragraphs of its opinion. It focused on the findings that (1) Canale disclosed "agent status messages of these claims"; and (2) the claims corresponding to the count required only that the agent status messages have the same "content" throughout their transmission. The Board did not expressly construe the limitation, "agent status messages," before it determined that Canale reads on that limitation and the count. Gechter appeals from the Board's decision, arguing that the Board failed to interpret properly the limitation in light of his specification and therefore clearly erred in finding anticipation. Davidson cross-appeals, contending [*1457] that if this court finds Gechter's claims corresponding to the count patentable over Canale, then it should also find that Davidson's claims corresponding to the count are patentable over Canale by reading the count in light of Davidson's specification. [HN1] We have jurisdiction over this appeal pursuant to *35 U.S.C. § 141* (1994) and *28 U.S.C. § 1295*(a)(4)(A) (1994).

n2 The PTO may, during the course of an interference, determine the patentability of any claim involved in the interference. See *Rowe v. Dror, 112 F.3d 473,* slip op. at 5 (Fed. Cir. 1997); see also 37 C.F.R. § § 1.633(a), *1.641* (1996). Because the parties stipulated that the patentability of all of the dependent claims would rise or fall with that of the independent claims, the Final Decision of the Board was dispositive of the entire interference.

[**5]

I.

[HN2] Under *35 U.S.C. § 102,* every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim. [HN3] *In re Bond, 910 F.2d 831, 832, 15 U.S.P.Q.2D (BNA) 1566, 1567 (Fed. Cir. 1990).* As the Board's finding of anticipation presents a question of fact, this court's review is limited to deciding whether such finding was clearly erroneous. *In re King, 801 F.2d 1324, 1326, 231 U.S.P.Q. (BNA) 136, 138 (Fed. Cir. 1986).* Implicit in our review of the Board's anticipation analysis is that the claim must first have been correctly construed to define the scope and meaning of each contested limitation. See, e.g., *In re Paulsen, 30 F.3d 1475, 1479, 31 U.S.P.Q.2D (BNA) 1671, 1674 (Fed. Cir. 1994)* ("To properly compare [an allegedly anticipatory prior art reference] with the claims at issue, we must construe the term 'computer' to ascertain its scope and meaning."). Claim construction is a question of law and therefore reviewed *de novo. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979, 34 U.S.P.Q.2D (BNA) 1321, 1329 (Fed. Cir. 1995)* (in banc), aff'd, *134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996).*

A. The relevant statute and our own case law compel our vacatur of the Board's decision. By appealing the [**6] Board's decision to this court, Gechter invoked our jurisdiction under [HN4] *35 U.S.C. § 141,* which provides that "[a] party to an interference dissatisfied with the decision of the Board of Patent Appeals and Interferences on the interference may appeal the decision to the United States Court of Appeals for the Federal Circuit." See also *37 C.F.R. § 1.301* (1996). It then becomes our duty to review that decision for error. *35 U.S.C. § 144* (1994) ("The United States Court of Appeals for the Federal Circuit shall review the decision from which an appeal is taken on the record before the Patent and Trademark Office." (emphasis added)). [HN5] For an appellate court to fulfill its role of judicial review, it must have a clear understanding of the grounds for the decision being reviewed. Cf. *Atlantic Thermoplastics Co. v. Faytex Corp., 5 F.3d 1477, 1479, 28 U.S.P.Q.2D (BNA) 1343, 1345 (Fed. Cir. 1993)* ("Here the court's opinion is too conclusory and sparse to provide a factual basis for determining whether the invention was on sale . . . ."). When the opinion explaining the decision lacks adequate fact findings, meaningful review is not possible, frustrating the very purpose of appellate review as well as [**7] this court's compliance with its statutory mandate. Id. Therefore, the statute's mandate to "review" implies inherent power in this court to require that the Board's decision be capable of review.

[HN6] Necessary findings must be expressed with sufficient particularity to enable our court, without resort to speculation, to understand the reasoning of the Board, and to determine whether it applied the law correctly and whether the evidence supported the underlying and ultimate fact findings. If either the crucial findings on underlying factual issues or the ultimate finding of anticipation is clearly erroneous, the decision must be reversed. See, e.g., *King, 801 F.2d at 1327, 231 U.S.P.Q. (BNA) at 139* ("The board's finding of anticipation . . . cannot be clearly erroneous in the face of the supporting

evidence."). Similarly, if the claims were misconstrued, a finding of anticipation must be reversed unless the error was harmless. Rowe, slip op. at 14 (Because of improper claim construction, "the Board clearly erred in its conclusion that the [prior art] patent anticipated Rowe's claims corresponding to the interference count[.]"); see also *In re Graves, 69 F.3d 1147, 1152-53, 36 U.S.P.Q.2D (BNA) 1697, 1702* [**8] *(Fed. Cir. 1995)* ("In summary, we find that the Board's claim construction is reasonable, and its determination what [the prior art] teaches is not clearly erroneous. We cannot say, therefore, that the Board's conclusion that [the prior art] anticipates claims 4 and 6 is clearly erroneous.").

[*1458] Although we have said we review decisions, not opinions, *King Instrument Corp. v. Otari Corp., 767 F.2d 853, 862, 226 U.S.P.Q. (BNA) 402, 408 (Fed. Cir. 1985),* [HN7] like a district court opinion, a Board opinion must contain sufficient findings and reasoning to permit meaningful appellate scrutiny. See *Bond, 910 F.2d at 833, 15 U.S.P.Q.2D (BNA) at 1568* (because the Board made no finding that the delay means in the specification and that embodied in the prior art reference were structurally equivalent, "its decision as to the anticipation of claim 1 is deficient and must be vacated"); cf. *In re Alton, 76 F.3d 1168, 1176, 37 U.S.P.Q.2D (BNA) 1578, 1584 (Fed. Cir. 1996)* (Board's decision vacated for failing to articulate adequate reasons of why applicant's evidence failed to rebut the Board's prima facie case of inadequate description.).

B. Analogous authority also supports our disposition. [HN8] The standard of review of district [**9] court fact findings, set forth in *Federal Rule of Civil Procedure 52(a)*, is the "clearly erroneous" standard. That is the same standard of review we apply to Board fact finding in both anticipation and obviousness contexts. [HN9] Thus, Rule 52(a) and case law construing its requirements are instructive, even though not controlling, here. That rule requires that "in all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon," *Fed. R. Civ. P. 52(a)* (emphasis added). Rule 52(a)'s purpose is, inter alia, to provide the appellate court with an adequate basis for review. See *Pretty Punch Shoppettes, Inc. v. Hauk, 844 F.2d 782, 784, 6 U.S.P.Q.2D (BNA) 1563, 1565 (Fed. Cir. 1988)* ("The trial court must provide sufficient factual findings such that we may meaningfully review the merits of its order."). A district court therefore may not merely state its findings in conclusory terms, but must provide sufficient detail to elucidate the reasoning by which the court reached its ultimate finding on an issue of fact or conclusion on an issue of law; otherwise, the appellate court is unable to carry out its [**10] appellate review function. Indeed, as to the facts it must also find subsidiary facts "specially," and not just the ultimate fact, here of anticipation. If it fails to do so, its decision will ordinarily be vacated.

The same rule governs when a conclusion on a crucial issue of law is omitted. For example, in *Graco, Inc. v. Binks Manufacturing Co., 60 F.3d 785, 35 U.S.P.Q.2D (BNA) 1255 (Fed. Cir. 1995),* we vacated the district court's judgment of patent infringement, because the district court's opinion was "absolutely devoid of any discussion of claim construction." *Id. at 791, 35 U.S.P.Q.2D (BNA) at 1259.* In addition, the district court had focused its infringement analysis on only one claim limitation, and had concluded, without analysis, that that claim limitation was met by the accused device. *Id. at 791, 35 U.S.P.Q.2D (BNA) at 1259-60.* After noting that such a conclusory finding was entirely inadequate under *Fed. R. Civ. P. 52(a)*, we concluded: "The entire omission of a claim construction analysis from the opinion, and the conclusory factual findings on infringement, each provide an independent basis for remand. Because insufficient findings preclude meaningful review by this court, we remand." Id.; see also [**11] *Oakley, Inc. v. International Tropic-Cal, Inc., 923 F.2d 167, 168, 17 U.S.P.Q.2D (BNA) 1401, 1403 (Fed. Cir. 1991)* (preliminary injunction vacated because district court's findings of fact and conclusions of law were insufficient to allow meaningful appellate review).

Similarly, in *Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 228 U.S.P.Q. (BNA) 90 (Fed. Cir. 1985),* we vacated the district court's invalidity decision under *35 U.S.C. § 103* (1994) for failure to set forth findings on the four factual inquiries delineated in *Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 U.S.P.Q. (BNA) 459, 467, 15 L. Ed. 2d 545, 86 S. Ct. 684 (1966).* In assessing the adequacy of the lower court's findings to support its obviousness determination, we reasoned that "we must be convinced from the opinion that the district court actually applied Graham and must be presented with enough express and necessarily implied findings to know the basis of the trial court's opinion." *Loctite, 781 F.2d at 873, 228 U.S.P.Q. (BNA) at 98.* In Loctite, because the district court "virtually abandoned" the Graham fact finding requirements, we vacated its obviousness holding for [*1459] failure to comply with Rule 52(a) and remanded for the district court to make specific findings for each Graham [**12] inquiry. Id.

In light of this court's statutory mandate to "review" decisions from the Board, we see no reason in law or logic to apply a less demanding version of the fact finding standard to the Board's decisions any more than we would apply a lesser version of the clearly erroneous review standard. As we have said, "the decisions of the PTO boards have been reviewed on the record [by this

court], by the same standards as applied to a decision from a district court[.]" *In re Lueders, 111 F.3d 1569,* slip op. at 12-13 (Fed. Cir. 1997) (discussing obviousness); see *35 U.S.C. § 144;* see also 9A Charles A. Wright & Arthur R. Miller, Federal Practice & Procedure § 2573, at 484-85 (1995) ("[Rule 52's] application to patent cases has never been doubted, and a principle substantially similar to Rule 52 governs the effect to be given the findings of the Patent Office in the district court." (footnotes omitted)). It is, of course, true that the Board is not bound by the Federal Rules of Civil Procedure, which by their terms apply only to the district courts. Nor, like the PTO Trademark Trial and Appeal Board, has the Board voluntarily bound itself to them. See *37 C.F.R. §* [**13] *2.116* (1996). But the Board must nevertheless meet an equivalent standard.

From a practical, judicial policy standpoint, moreover, patentability (validity) issues such as anticipation, whether decided by the Board or by district courts, should be reviewed similarly. If we did not require the Board to adhere to the same level of specificity in explicit fact findings and legal conclusions to support an anticipation finding, appellate review of the very same claim might produce disparate results, depending simply on which tribunal decided the issue. See Leuders, slip op. at 18-19 ("clear error" standard of review should apply to Board fact findings in order to maintain consistency with standard of review for district court fact findings). Our holding avoids this kind of disparity.

Nor does the standard we apply today exceed that applied to many other administrative tribunals. "It is well established that [HN10] agencies have a duty to provide reviewing courts with a sufficient explanation for their decisions so that those decisions may be judged against the relevant statutory standards, and that failure to provide such an explanation is grounds for striking down the action." *Mullins v. United* [**14] *States Dep't of Energy, 50 F.3d 990, 992 (Fed. Cir. 1995)* (citing *SEC v. Chenery Corp., 318 U.S. 80, 94, 87 L. Ed. 626, 63 S. Ct. 454 (1943)).* Furthermore, we assume the Board's ability to set forth fact findings and conclusions of law at the level of specificity equal to that required by Rule 52(a). Many Board members, now known as "Administrative Patent Judges," are experienced former senior examiners. Due to their technical expertise as well as their opinion writing experience as administrative judges, they are more than capable of providing the adequate fact finding required by our cases reviewing the PTO Board, and also called for regarding other tribunals in Rule 52(a) and administrative law decisions. See *35 U.S.C. § 7*(a) (1994) ("The examiners-in-chief shall be persons of competent legal knowledge . . . ."). Moreover, in the past we have required administrative judges of other boards to set forth adequate findings of fact to support their decisions. See, e.g., *RMI, Inc. v. United States, 800 F.2d 246, 250 (Fed. Cir. 1986)* (decision vacated and remanded to the Armed Services Board of Contract Appeals because of inadequate findings of fact).

II.

Judged under the standard set forth above, the Board's opinion lacks the level of specificity [**15] necessary for our review. In concluding that the claims corresponding to the count were unpatentable over Canale under *35 U.S.C. § 102,* the Board provided only the following, limited analysis:

With respect to Gechter's argument, it is considered that the [prior art] reference discloses the agent status messages of these claims. . . . Although the electrical signals representative of the [prior art] messages may be modified by controller 102, the message content of the agent status messages derived from the agent positions 103-1 to 103-n (the line status [*1460] changes as they occur) remains the same when forwarded to the receiving means 108 (station set interface). Thus, the agent status messages received by means 108 are the same messages originating with the agent stations.

Notably absent from the Board's opinion is any explanation for whether, how, and why Canale contains each of the other limitations of the claim. Yet the Board does not say their presence in Canale was conceded. Moreover, the Board's only other attempted justification appears in a footnote to its opinion, asserting that "neither party has argued that the Canale reference does not include a written description [**16] of an equivalent structure" of the means-plus-function recitations in the independent claims. Nevertheless, [HN11] to hold that a prior art reference anticipates a claim, the Board must expressly find that every limitation in the claim was identically shown in the single reference. *Bond, 910 F.2d at 832, 15 U.S.P.Q.2D (BNA) at 1567.*

In the present case, the Board's opinion lacks a claim construction, makes conclusory findings relating to anticipation, and omits any analysis on several limitations. For example, the Board opinion does not separately construe the term "agent status messages" before finding that Canale discloses just such "agent status messages." In addition, the Board never construed the scope of the structures disclosed in the specification for the claimed "receiving means," nor did the Board expressly find that the "receiving means" disclosed in the specification was structurally equivalent to that embodied in Canale. Moreover, the Board's opinion also failed to define the exact function of the receiving means, as well as to find that Canale disclosed the identical function. See *Pennwalt Corp. v. Durand-*

Wayland, Inc., 833 F.2d 931, 934, 4 U.S.P.Q.2D (BNA) 1737, 1739 (Fed. Cir. 1987) (in banc) [**17] (means-plus-function limitation covers structure that performs the identical function and is the same structure described in the specification or an equivalent thereof). The parties contest these issues on appeal, but the relevant findings were omitted from the Board's opinion. In Bond, this court vacated the Board's anticipation decision because it failed to make one particular subsidiary finding. In that case, the Board determined that a prior art reference anticipated the applicant's claimed telephone answering machine, finding that the reference disclosed the claimed "delay means." *910 F.2d at 833, 15 U.S.P.Q.2D (BNA) at 1568.* The delay means disclosed in the reference, however, was not identical to the delay means in the specification. This court vacated the Board's anticipation decision because the Board made no specific finding that, pursuant to *35 U.S.C. § 112,* P 6 (1994), the delay means in the specification and that embodied in the prior art reference were structurally equivalent. Id. Here, the Board's opinion omits not one, but several crucial findings. We therefore must vacate and remand.

CONCLUSION

In sum, we hold that [HN12] the Board is required to set forth in its opinions specific [**18] findings of fact and conclusions of law adequate to form a basis for our review. In particular, we expect that the Board's anticipation analysis be conducted on a limitation by limitation basis, with specific fact findings for each contested limitation and satisfactory explanations for such findings. n3 Claim construction must also be explicit, at least as to any construction disputed by parties to the interference (or an applicant or patentee in an ex parte proceeding).

n3 While not directly presented here, obviousness determinations, when appropriate, similarly must rest on fact findings, adequately explained, for each of the relevant obviousness factors in the Supreme Court's decision in *Graham, 383 U.S. at 17-18, 148 U.S.P.Q. (BNA) at 467,* and its progeny in this court, see, e.g., *Loctite, 781 F.2d at 872, 228 U.S.P.Q. (BNA) at 97.*

VACATED AND REMANDED.

COSTS

Each party shall bear its own costs for this appeal.

LEXSEE 75 F.3D 1558

PPG INDUSTRIES, INC., Plaintiff-Appellee, v. GUARDIAN INDUSTRIES CORPORATION, Defendant-Appellant.

95-1222

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

75 F.3d 1558; 1996 U.S. App. LEXIS 1693; 37 U.S.P.Q.2D (BNA) 1618

February 6, 1996, Decided

PRIOR HISTORY: [**1] Appealed from: United States District Court Western District of Pennsylvania. Judge Lancaster.

DISPOSITION: AFFIRMED.

CASE SUMMARY:

PROCEDURAL POSTURE: Defendant appealed from judgment of the United States District Court for the Western District of Pennsylvania, which granted plaintiff's motion for a preliminary injunction barring defendant's marketing or use of its automobile glass, pending litigation of plaintiff's patent infringement claim.

OVERVIEW: Plaintiff, which owned a patent on automobile glass, moved for a preliminary injunction barring defendant from manufacturing or marketing a similar type of glass pending litigation on the merits of plaintiff's patent infringement action. Defendant argued plaintiff's patent was invalid. Defendant contended that plaintiff's patent claim specifications were not sufficiently enabling, as certain calculations in the specifications were erroneous. The court first held that, despite the error in the claims specifications, the critical limitations of the claims requirements covered defendant's product. The court then held that plaintiff's claims gave clear notice as to their scope, and thus met the requirements of particularity. The court also held the patent's claim specifications were sufficiently enabling despite calculation errors, as the specifications would lead an individual to produce the claimed patent without undue experimentation. The court then upheld the trial court's finding that plaintiff's likely success on its infringement claim weighed in favor of granting a preliminary injunction.

OUTCOME: The judgment was affirmed, as relevant factors weighed in favor of granting preliminary injunction.

LexisNexis(R) Headnotes

Patent Law > Claims & Specifications > Definiteness > General Overview

[HN1] Paragraph 2 of *35 U.S.C.S. § 112* is essentially a requirement for precision and definiteness of claim language. The requirement is that the language of the claims must make it clear what subject matter they encompass.

Patent Law > Claims & Specifications > Definiteness > Precision Standards

[HN2] Under patent law, claims meet requirements for definiteness when they reasonably apprise those skilled in the art of both the utilization and scope of the invention, and when the language is as precise as the subject matter permits.

Patent Law > Claims & Specifications > Enablement Requirement > Standards & Tests

Patent Law > Claims & Specifications > Definiteness > General Overview

Patent Law > Claims & Specifications > Description Requirement > General Overview

[HN3] The enablement requirement of *35 U.S.C.S. § 112,* P 1, requires that the specification contain a description of the manner and process of making and using the invention, in such full, clear, concise, and exact

terms as to enable any person skilled in the art to which it pertains to make and use the invention.

Patent Law > Claims & Specifications > Enablement Requirement > Standards & Tests
[HN4] In order to be enabling under patent law, a specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

Patent Law > Claims & Specifications > Enablement Requirement > Proof
Patent Law > Jurisdiction & Review > Subject Matter Jurisdiction > Appeals
Patent Law > Jurisdiction & Review > Standards of Review > General Overview
[HN5] Under patent law, enablement is a question of law that the United States Court of Appeals for the Federal Circuit independently reviews, although the issue is based upon underlying factual findings, which are reviewed for clear error.

Patent Law > Claims & Specifications > Enablement Requirement > Scope
Patent Law > Claims & Specifications > Enablement Requirement > Standards & Tests
Patent Law > U.S. Patent & Trademark Office Proceedings > Reissues > General Overview
[HN6] In applying patent law to unpredictable art areas, the United States Court of Appeals for the Federal Circuit refuses to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. Enablement is lacking in those cases because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. However, the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation must not be unduly extensive.

Patent Law > Claims & Specifications > Enablement Requirement > Standards & Tests
[HN7] In determining whether a claim specification meets the enablement requirements of patent law, where the specification provides guidance in selecting the operating parameters that would yield the claimed result, the experimentation required to make a particular embodiment is not "undue."

Patent Law > Infringement Actions > Defenses > Patent Invalidity > Validity Presumption
Patent Law > Inequitable Conduct > Effect, Materiality & Scienter > General Overview
[HN8] In order to invalidate a patent, the ultimate question a court must address is whether the challenger's evidence of invalidity is sufficiently persuasive that it is likely to overcome the presumption of patent validity.

Patent Law > Anticipation & Novelty > Elements
Patent Law > Claims & Specifications > Enablement Requirement > Standards & Tests
[HN9] To anticipate a claim under patent law, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.

COUNSEL: Arland T. Stein, Reed Smith Shaw & McClay, of Pittsburgh, Pennsylvania, argued for plaintiff-appellee. With him on the brief was Stanley D. Ference III. Of counsel was Cynthia E. Kernick. Also on the brief was Mark Levin, PPG Industries, Inc., of Pittsburgh, Pennsylvania.

Daniel W. Vittum, Jr., P.C., Kirkland & Ellis, of Chicago, Illinois, argued for defendant-appellant. With him on the brief was Jeffrey D. Mills.

JUDGES: Before MICHEL, SCHALL, and BRYSON, Circuit Judges.

OPINIONBY: BRYSON

OPINION: [*1560] BRYSON, Circuit Judge.

This case concerns a dispute between two major manufacturers of automotive glass; the dispute revolves around glass compositions known as "solar control glass," which have the highly desirable characteristics of filtering out most of the sun's ultraviolet and infrared radiation while transmitting most of the light in the visible part of the spectrum. Appellee PPG Industries, Inc., which holds a patent on a composition of solar control glass, sued appellant Guardian Industries Corporation for patent infringement and obtained a preliminary injunction from the [**2] United States District Court for the Western District of Pennsylvania. The injunction prohibits Guardian from making, using, or selling its own composition of solar control glass. We conclude that the district court did not abuse its discretion in granting preliminary injunctive relief to PPG, and we therefore affirm the order of the district court.

I

On August 31, 1993, the Patent and Trademark Office issued U.S. Patent No. *5,240,886* (the *'886*

patent), which was assigned to PPG. Shortly after obtaining the patent, PPG advised Guardian that it believed Guardian's solar control glass, known as "Solar Management Glass" (SMG), infringed PPG's rights under the patent. Litigation followed, and after a five-day hearing the district court granted PPG's motion for a preliminary injunction.

The district court found that PPG had established a likelihood of success on the merits by making a strong showing that SMG infringed PPG's rights under the patent and that the patent was not invalid. In light of PPG's showing on the merits, the court held that PPG was entitled to a presumption that it would suffer irreparable harm from Guardian's continued infringement. The court also found that [**3] the balance of hardships and the public interest weighed in favor of granting PPG's request for preliminary injunctive relief. Guardian brought this appeal, contesting the district court's ruling on each of those points.

II

A

The issue to which the parties devote the most attention is whether Guardian infringed claim 1 of the *'886* patent and dependent claims 3 and 4. Claim 1 of the *'886* patent defines a glass composition consisting of soda-lime-silica glass to which is added a set of ingredients that have the effect of selectively filtering out most of the sun's ultraviolet radiation. The filtering ingredients are identified in the claim as cerium (in the form of cerium oxide (CeO2) and iron (in the ferric (Fe2O3) state). The claim requires that the composition have a total iron content of at least 0.85 percent by weight, and that the ratio of iron in the ferrous (FeO) state to total iron (known as the redox ratio) be no greater than 0.275. In full text, the claim reads as follows:

1. A green tinted, ultraviolet absorbing glass having a base glass composition consisting essentially of:

SiO[2]	68-75 weight %
Na[2]O	10-20
CaO	5-15
MgO	0-5
Al[2]O[3]	0-5
K[2]O	0-5

[*1561] and a colorant portion consisting essentially of: [**4]

CeO[2]	Less than 0.5 weight %
Total Iron (as Fe[2]O[3])	Greater than 0.85 weight %
FeO/total iron	Less than 0.275.

exhibiting ultraviolet transmittance no greater than 31 percent (300 to 390 nanometers) and luminous transmittance (illuminant A) of at least 70 percent, both at a reference thickness of 3.9 millimeters.

Dependent claim 3 adds the limitation that the dominant wavelength of the light transmitted by the glass must be between 495 and 535 nanometers (the green color range of the spectrum), and dependent claim 4 adds the requirement that the glass must exhibit a total solar energy transmittance (including ultraviolet, visible, and infrared radiation) of less than 45 percent at a reference thickness of 3.9 millimeters.

The ultraviolet and visible light transmission requirements set forth in the claims are those established by the automotive industry as the minimum standards for acceptable solar control glass. Prior to the *'886* invention (and Guardian's SMG glass), solar control glass was often made with a significant amount of cerium, a rare earth element, in the form of cerium oxide. The principal benefit of the invention claimed in the *'886* patent, as explained in the specification, is that it permits a

manufacturer of solar control glass to meet [**5] industry standards while adding either no cerium or relatively little cerium to the glass. Minimizing the amount of cerium used in the glass is valuable because cerium is expensive and because it has the undesirable effect, after long-term exposure to ultraviolet radiation, of darkening the glass in which it is present.

The specification of the *'886* patent contains a set of examples of compositions falling within the scope of claim 1 of the patent. The examples include several compositions containing relatively small amounts of cerium (between 0.27 and 0.31 percent cerium by weight) and one composition containing essentially no cerium. Each of the examples satisfies the transmittance requirements of the claim for visible light and ultraviolet radiation. The example that contains no cerium, however, shows a particularly low redox ratio. A low redox ratio, together with a relatively large amount of iron, has the effect of compensating for the absence of cerium in filtering out ultraviolet radiation. With respect to the no-cerium example, the specification further states that

> the very low ferrous to total iron ratio required when no cerium is used may be difficult to attain [**6] in some melting furnaces. Therefore, it is preferred that a small amount of cerium be used to yield the desired reduction in ultraviolet transmittance without requiring an unduly low ferrous to total iron ratio.

While the *'886* patent application was pending before the PTO, PPG obtained a sample of Guardian's SMG glass and tested it. When PPG's tests showed that the SMG sample did not meet the automobile manufacturers' standards for ultraviolet transmittance, PPG advised Guardian of those results. Guardian responded that under its tests SMG met the 31 percent ultraviolet transmittance requirement for the 300 to 390 nanometer range. When PPG re-examined its testing procedures, it discovered that the software it was using in its testing equipment was flawed and that as a result the testing equipment had made an error in calculating not only the ultraviolet transmittance of the SMG sample, but also the ultraviolet transmittance of each of the examples set forth in the *'886* patent specification. Because of the software error, the ultraviolet transmittance reported in each example was about three percent too high; thus, the glass tested in each example was actually filtering out [**7] about three percent more ultraviolet radiation than the testing equipment indicated. That error had led the inventors to suggest in the specification that a glass meeting the limitations of the patent and containing no cerium at all might be difficult to make commercially, as it would require a redox ratio that would be hard to achieve in some commercial furnaces. In fact, however, the transmittance limitations of the claims for a no-cerium glass are not as difficult to satisfy as the specification suggests, because after an adjustment is made for the three percent calculation error, the redox ratio for the no-cerium embodiment [*1562] does not have to be as low as the specification indicates.

Based on the three percent calculation error, Guardian argues that the claims of the *'886* patent do not cover SMG. If the claims are read in light of the specification, Guardian argues, they cannot be construed to apply to SMG, because the examples in the specification make clear that the inventors did not believe that a glass having the composition of SMG would satisfy the 31 percent ultraviolet transmission requirement.

The problem with Guardian's argument is that the claims simply cannot be construed [**8] as Guardian suggests. By their plain terms, the claims read on SMG: the critical limitations require that the glass contain less than 0.5 percent cerium and more than 0.85 percent iron, that the redox ratio of the iron components be less than 0.275, that the ultraviolet transmittance be no greater than 31 percent, and that the visible light transmittance be at least 70 percent. SMG satisfies all of those limitations and thus infringes claim 1 of the *'886* patent. Moreover, because the dominant wavelength transmitted by SMG is within the green range (495 to 535 nanometers) and because SMG's total solar energy transmittance at the 3.9 millimeter reference thickness is less than 45 percent, it falls within the limitations of dependent claims 3 and 4 as well.

It is true that if Guardian's SMG glass is tested with the same flawed testing equipment that was used to prepare the examples in the *'886* patent specification, SMG's ultraviolet transmittance would appear to be above the 31 percent maximum set forth in the claims. But the *'886* patent claims are not qualified in that manner; the claims cover glass that transmits no more than 31 percent of the sun's ultraviolet radiation, not glass [**9] that is measured at no more than 31 percent ultraviolet transmittance with PPG's flawed testing system. Because it is undisputed that SMG transmits no more than 31 percent of the sun's ultraviolet radiation over the wavelength range of 300 to 390 nanometers, and because that is the way the ultraviolet transmittance limitation is specified in the patent claims, the claims cannot be construed in a way that renders SMG non-infringing.

B

In the alternative, Guardian argues that if the claims are interpreted to read on SMG, the patent is invalid under section 112 of the Patent Act, *35 U.S.C. § 112.* Guardian makes three arguments in support of its section 112 claim. First, Guardian contends that the claims run afoul of the requirement of particularity and distinctness in paragraph 2 of section 112 because they fail to point out and distinctly claim what the inventors regarded as their invention. Second, Guardian argues that the claims violate paragraph 2 of section 112 for the additional reason that the inventors failed to state the method they used to measure the ultraviolet transmittance of the invention. Third, Guardian asserts that the patent is invalid because, in order for the [**10] claims to read on SMG, the claims must be interpreted as extending beyond the invention disclosed in the specification. In its reply brief, Guardian makes explicit that its third argument is based on the "enablement" requirement of paragraph 1 of section 112, not the "written description" requirement that appears in the same paragraph.

We reject each of the section 112 arguments on which Guardian relies. First, paragraph two of section 112 [HN1] "is essentially a requirement for precision and definiteness of claim language," *In re Borkowski, 57 C.C.P.A. 946, 422 F.2d 904, 909, 164 U.S.P.Q. (BNA) 642, 646 (CCPA 1970)* (emphasis in original); the "requirement is that the language of the claims must make it clear what subject matter they encompass," *In re Hammack, 57 C.C.P.A. 1225, 427 F.2d 1378, 1382, 166 U.S.P.Q. (BNA) 204, 208 (CCPA 1970).*

There is nothing imprecise or indefinite about the claim language in the *'886* patent. The claims are quite precise in quantifying the essential ingredients and transmittance tolerances of the claimed compositions: on their face, the claims give clear notice of what compositions fall within their scope. [HN2] Because the claims "reasonably apprise those skilled in the art both of the utilization and [**11] scope of the invention," and because "the language is as precise as the [*1563] subject matter permits," *Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 U.S.P.Q. (BNA) 634, 641 (Fed. Cir. 1985)* (internal quotation omitted), cert. dismissed, *474 U.S. 976 (1985),* the claims are not invalid for indefiniteness.

Guardian argues that the patent nonetheless violates paragraph 2 of section 112 because the inventors would not have believed at the time of their application that glass having the composition of SMG could meet the transmittance limitations of the claims. That misconception on the part of the inventors, however, does not mean that they failed to "distinctly claim[] the subject matter which [they] regarded as [their] invention." *35 U.S.C. § 112,* P2. The inventors regarded their invention as a glass containing filtering ingredients within the defined composition ranges and producing an ultraviolet transmittance of no more than 31 percent and a visible light transmittance of at least 70 percent, and that is what they claimed. Guardian relies on cases in which the claims included "a substantial measure of inoperatives," *In re Corkill, 771 F.2d 1496, 1501,* [**12] *226 U.S.P.Q. (BNA) 1005, 1009 (Fed. Cir. 1985),* or cases in which "some material submitted by applicant, other than his specification, shows that a claim does not correspond in scope with what he regards as his invention," *In re Conley, 490 F.2d 972, 976, 180 U.S.P.Q. (BNA) 454, 457 (CCPA 1974)* (emphasis in original; citing *In re Cormany, 476 F.2d 998, 177 U.S.P.Q. (BNA) 450 (CCPA 1973),* and *In re Prater, 56 C.C.P.A. 1381, 415 F.2d 1393, 162 U.S.P.Q. (BNA) 541 (CCPA 1973)).* In this case, by contrast, the claims were written in a manner that required all the embodiments to be operative; the claims set out exactly what the inventors intended to claim as their invention; and Guardian does not point to any statement by the applicants outside the specification that indicates that they did not intend to claim all species having the recited limitations. Moreover, nothing in the specification renders any of the claim language ambiguous, such that a person skilled in the art would be uncertain about "what subject matter falls within the scope of the claims." *In re Miller, 58 C.C.P.A. 1182, 441 F.2d 689, 692, 169 U.S.P.Q. (BNA) 597, 599 (CCPA 1971);* see *In re Moore, 58 C.C.P.A. 1042, 439 F.2d 1232, 1235, 169 U.S.P.Q. (BNA) 236, 238 (CCPA 1971).* There is therefore no force to Guardian's [**13] argument that the claims did not accurately and distinctly set out what the inventors regarded as their invention.

Second, the patent is not rendered invalid on the ground that the inventors failed to specify the method to be used in measuring the ultraviolet transmittance set forth in the claims. The evidence at the preliminary injunction hearing established that, setting aside the equipment error that plagued PPG's testing procedures, all of the conventional methods of testing ultraviolet transmittance produce essentially identical results. Accordingly, the claim limitation of no more than 31 percent ultraviolet transmittance, in conjunction with the other limitations, is sufficiently definite to put the public on fair notice of what compositions fall within the scope of the claims. See *Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 U.S.P.Q. (BNA) 81, 94-95 (Fed. Cir. 1986),* cert. denied, *480 U.S. 947, 94 L. Ed. 2d 792, 107 S. Ct. 1606 (1987).*

Third, the specification satisfies the enablement requirement of section 112, paragraph 1, [HN3] which requires that the specification contain a description "of

the manner and process of making and using [the invention], in such full, clear, concise, [**14] and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same." *35 U.S.C. § 112,* P1. The specification of the *'886* patent describes in ample detail how to make and use the invention with respect to the seven specific embodiments set forth in the experimental examples. And Guardian does not dispute that the specification enables all embodiments falling within the other claim limitations and having an ultraviolet transmittance of 28 percent or less (which is the transmittance that PPG's flawed testing equipment reported as 31 percent). The only contested issue is whether the *'886* patent must be held invalid on the ground that the specification fails to satisfy the enablement requirement with respect to embodiments having an actual ultraviolet transmittance of less than 31 percent, [*1564] but which PPG's equipment would have reported as more than 31 percent.

In pressing its enablement argument, Guardian focuses on the portion of the specification that suggests a particularly low redox ratio is necessary to satisfy the ultraviolet transmittance limitation if the patented invention is made without any cerium. The test results and the statement [**15] on which Guardian relies are products of PPG's software error; the effect of the error was to make the ultraviolet transmittance figures appear artificially high and thus to make it appear that in order to attain the 31 percent ultraviolet transmittance limitation in the claims, the composition would need more iron and a lower redox ratio, both of which have the effect of reducing ultraviolet transmittance.

We are not persuaded that the calculation error and the statements in the specification regarding the need for a low redox ratio in a no-cerium embodiment of the invention give rise to a violation of the enablement requirement. It is true that, [HN4] in order to be enabling, a specification "must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright, 999 F.2d 1557, 1561, 27 U.S.P.Q.2D (BNA) 1510, 1513 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 495-96, 20 U.S.P.Q.2D (BNA) 1438, 1444-45 (Fed. Cir. 1991).* Moreover, Guardian is correct that a careful reader of the specification could well conclude that a glass with the iron content and redox ratio of SMG would not be likely to satisfy the ultraviolet transmittance [**16] limitation of the claims. The district court found, however, that PPG's calculation error was "harmless, inconsequential, and easily detectable by anyone who was skilled in the art of processing solar controlled glass." We interpret that statement as a factual finding that PPG's error could be discovered without "undue experimentation" by a person having ordinary skill in the art, and thus that the enablement requirement of section 112 was satisfied. See *In re Vaeck, 947 F.2d at 495, 20 U.S.P.Q.2D (BNA) at 1444* [HN5] ("Enablement . . . is a question of law which we independently review, although based upon underlying factual findings which we review for clear error.").

In light of the district court's finding, we cannot agree with Guardian that the specification of the *'886* patent does not "teach those skilled in the art how to make and use the full scope of the claimed invention." *In re Wright, 999 F.2d at 1561; 27 U.S.P.Q.2D (BNA) at 1513.* [HN6] In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments [**17] across the full scope of the claim. See, e.g., *In re Goodman, 11 F.3d 1046, 1050-52, 29 U.S.P.Q.2D (BNA) 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212-14, 18 U.S.P.Q.2D (BNA) 1016, 1026-28* (Fed. Cir.), cert. denied, *502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 U.S.P.Q.2D (BNA) at 1445.* Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." *Atlas Powder Co. v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 U.S.P.Q. (BNA) 409, 413 (Fed. Cir. 1984).* The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction [**18] in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 U.S.P.Q. (BNA) 804, 807 (1982).

In this case, the district court was justified in finding that undue experimentation would not be required to make an embodiment of the *'886* patent having the same composition and transmittance properties as SMG. One

of the examples in the specification describes [*1565] a glass containing no cerium, but having a lower redox ratio and a higher iron content than SMG. The specification teaches that as the iron content of the glass is reduced and the redox ratio rises, the glass transmits more ultraviolet radiation. A person reading the specification could therefore start with the no-cerium example and make a glass similar to SMG by simply lowering the iron content and allowing the redox ratio to rise until the ultraviolet transmittance reached the 31 percent limitation.

Another example given in the specification has roughly the same composition as SMG except that it contains a small amount of cerium. Following the principles taught in the specification, an experimenter could produce an embodiment of [**19] the *'886* patent with a composition and properties similar to SMG simply by keeping the iron content and the redox ratio fixed, and reducing the cerium content to zero. In preparing that embodiment, the experimenter would discover that the ultraviolet transmittance calculations for the examples found in the patent specification are a few percent too high, but that error would not affect the experimenter's ability to make the desired embodiment.

[HN7] Where the specification provides "guidance in selecting the operating parameters that would yield the claimed result," *In re Colianni, 561 F.2d 220, 224, 195 U.S.P.Q. (BNA) 150, 153 (CCPA 1977)* (Miller, J., concurring) (emphasis omitted), it is fair to conclude that the experimentation required to make a particular embodiment is not "undue." Although PPG's software error made it appear that commercial production of a no-cerium composition that satisfied the transmittance limitations would be difficult, the specification made it clear that such a composition could be made, and it indicated to one skilled in the art how to maintain low ultraviolet transmittance while minimizing the cerium content of the glass. Thus, the specification gave "considerable [**20] direction and guidance on how to practice [the] invention." *In re Wands, 858 F.2d 731, 740, 8 U.S.P.Q.2D (BNA) 1400, 1406 (Fed. Cir. 1988).*

In light of the guidance provided by the specification, this case is quite different from those in which enablement has been found lacking because of the need for "undue experimentation." See, e.g., *White Consol. Indus., Inc. v. Vega Servo-Control, Inc., 713 F.2d 788, 790-92, 218 U.S.P.Q. (BNA) 961, 962-64 (Fed. Cir. 1983)* (a requirement of 18 months to two years' work to practice the patented invention is "undue experimentation"); *In re Ghiron, 58 C.C.P.A. 1207, 442 F.2d 985, 992, 169 U.S.P.Q. (BNA) 723, 727-28 (CCPA 1971)* (a development period of "'many months or years . . . does not bespeak a routine operation but of extensive experimentation and development work'"). It was therefore reasonable for the district court to conclude that the patent was not invalid for lack of enablement.

C

Guardian next contends that it does not infringe PPG's rights under the *'886* patent, because SMG contains a sulfur compound that significantly affects its filtering properties, and the claims of the *'886* patent therefore do not read on SMG glass. The district court acknowledged [**21] that SMG contains sulfur, but it found that the sulfur contained in SMG has no material effect on the filtering properties of the glass.

Guardian contends that the district court committed clear error in the factual finding it made on the sulfur issue. The court's finding, however, was based on an extensive exploration of the issue through testimony and documents at the five-day preliminary injunction hearing. Although Guardian introduced documentary evidence that sulfur can affect the transmittance properties of glass, Guardian did not persuade the district court -- and has not persuaded us -- that those authorities prove that sulfur has such an effect when the redox ratio is as low as it is in Guardian's accused SMG product.

Guardian challenges the testimony of PPG's expert on the sulfur issue, but the court heard testimony by experts from both sides and found PPG's expert testimony more convincing. Because we do not find PPG's presentation on the sulfur issue inherently implausible, we are satisfied that the district court's finding on that issue is not clearly erroneous.

[*1566] D

Guardian's next argument is that PPG failed to satisfy its burden of showing that the *'886* patent [**22] is likely to survive challenges based on Guardian's defenses of anticipation and obviousness. Before the district court, Guardian argued that example 4 in Russian Patent No. 948,912 anticipated, or at least rendered obvious, claim 1 of the *'886* patent. Guardian urges that in rejecting its contention, the district court applied an erroneous legal standard and did not make sufficiently detailed factual findings to permit meaningful review by this court.

The district court concluded that there was no factual basis to support a finding of invalidity, because the Russian patent teaches that significant amounts of cerium and other rare earth elements that absorb ultraviolet light are necessary to reduce ultraviolet transmission to the level set forth in claim 1 of the *'886* patent. To be sure, the district court did not articulate the correct legal standard when it stated that to invalidate a patent the prior reference must "give the same knowledge and the same directions" as the challenged

patent. The ultimate question, however, [HN8] is whether the challenger's evidence of invalidity is sufficiently persuasive that it is likely to overcome the presumption of patent validity. See New England [**23] *Braiding Co. v. A.W. Chesterton Co., 970 F.2d 878, 883, 23 U.S.P.Q.2D (BNA) 1622, 1625 (Fed. Cir. 1992).* In view of the limited record presented to the district court on this issue, we agree with the court's conclusion that Guardian's argument based on the Russian patent failed to "raise[] a substantial question" of invalidity. Id.

[HN9] To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter. *Chester v. Miller, 906 F.2d 1574, 1576 n.2, 15 U.S.P.Q.2D (BNA) 1333, 1336 n.2 (Fed. Cir. 1990); In re Donohue, 766 F.2d 531, 533, 226 U.S.P.Q. (BNA) 619, 621 (Fed. Cir. 1985).* Guardian has not shown that the composition described in example 4 of the Russian patent meets the limitations of the claim, because that composition contains significant amounts of several rare earth elements that absorb ultraviolet radiation as well as visible light.

In presenting its defense of obviousness, Guardian again relied principally on the Russian patent. In the district court, however, Guardian did not demonstrate that the claimed invention would have been obvious to one skilled in the art in light of the disclosures [**24] in that reference. In its presentation to us, moreover, Guardian has not pointed to any evidence showing that the district court's factual finding that the Russian patent teaches away is clearly erroneous. Therefore, Guardian has failed to provide any basis for concluding that one skilled in the art would have been motivated to eliminate the additional rare earth elements recited in example 4 of the Russian patent and would have had a reasonable expectation of success in light of the prior art. See *In re Dow Chemical Co., 837 F.2d 469, 473, 5 U.S.P.Q.2D (BNA) 1529, 1531 (Fed. Cir. 1988).* For purposes of the preliminary injunction proceedings, PPG has thus satisfied its burden of showing a likelihood of success on the validity issue.

E

Guardian also challenges the district court's conclusion that PPG would suffer irreparable harm if preliminary injunctive relief were not granted. Because the district court found that PPG had made a clear showing that it was likely to prevail on the issues of patent validity and infringement, the court held that PPG was entitled to a presumption of irreparable harm. See *H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384, 390, 2 U.S.P.Q.2D* [**25] *(BNA) 1926, 1930 (Fed. Cir. 1987); Atlas Powder Co. v. Ireco Chemicals, 773 F.2d 1230, 1233, 227 U.S.P.Q. (BNA) 289, 292 (Fed. Cir. 1985).* In addition, the district court found that in the absence of injunctive relief PPG's significant position in the solar control glass market would be threatened.

Guardian places heavy reliance on this court's decision in *High Tech Medical Instrumentation, Inc. v. New Image Indus., Inc., 49 F.3d 1551, 33 U.S.P.Q.2D (BNA) 2005 (Fed. Cir. 1995),* where the court reversed a preliminary injunction in part because of an inadequate showing of irreparable harm. In that case, however, the court concluded that the [*1567] patentee was unlikely to succeed on the merits of its infringement claim and therefore held that the presumption of irreparable harm was inapplicable. *49 F.3d at 1556, 33 U.S.P.Q.2D (BNA) at 2009.* In this case, by contrast, we have upheld the district court's conclusion that PPG is likely to succeed at the merits stage on the issues of infringement and validity, and we agree that PPG's showing on those issues was sufficiently strong to invoke the presumption of irreparable harm. Because we agree with the district court that Guardian failed to rebut that presumption, [**26] we sustain the court's ruling that PPG met its burden of showing that it would suffer irreparable harm in the absence of an order granting preliminary injunctive relief.

F

Finally, Guardian argues that the balance of hardships and the public interest both counsel in favor of denying the injunction. The district court, however, considered both factors and reached the contrary conclusion, and we are not prepared to overturn that determination. The district court concluded that PPG would suffer significant harm from the denial of an injunction, while an injunction would be less burdensome for Guardian, as it would require only a temporary interruption in Guardian's production and sale of its SMG glass. With regard to the public interest, the court acknowledged that an injunction would deprive the public of one of the suppliers of solar control glass. The court, however, balanced that interest against the strong public policy favoring the enforcement of patent rights. Because the court found it unlikely that the injunction would result in a shortage of solar control glass, the court found that, on balance, the public interest favored PPG.

Guardian argues that PPG will be unable [**27] to satisfy the requirements of Guardian's customers, particularly the large automobile manufacturers, for solar control glass. To address that objection, however, the district court gave Guardian the right to return to court for relief from the preliminary injunction if Guardian were unable to fulfill its current contracts with automobile manufacturers, either with noninfringing compositions or by purchase from PPG on reasonable terms. Guardian made an initial request for temporary

relief from the injunction, which was granted. The record does not reflect that Guardian has made any further requests, although the district court has made clear that it would be prepared to entertain any such requests if they should be made. In the absence of a showing that the district court has been unresponsive to Guardian's interest in fulfilling its current contract obligations, or to the public's interest in obtaining an adequate supply of solar control glass, we cannot conclude that the district court abused its discretion in finding that both the balance of hardships and the public interest favor PPG.

III

The unusual circumstances surrounding the prosecution of the *'886* patent have made this [**28] preliminary injunction proceeding difficult. Nonetheless, we have carefully reviewed each of the numerous legal points that Guardian has raised in challenging the injunction, and we conclude that none of them requires that we upset the district court's order. Guardian will have an opportunity at the merits stage to present and expand upon the arguments it has made at the preliminary injunction stage, as well as any additional arguments that it chooses to present, and the district court will be able to give those arguments plenary consideration at that time. The record as it now stands, however, compels us to conclude that the district court did not abuse its discretion in granting the preliminary injunction.

AFFIRMED.